

EXHIBIT G

Scott A. Guelcher, Ph.D.

SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF KERN
CASE NO. S-1500-CV 279123 LHB

COLEEN M. PERRY,

PLAINTIFF

vs.

HUNG T. LUU, M.D.,
JOHNSON & JOHNSON, a New Jersey
Corporation; ETHICON, INC., a
New Jersey Corporation; and
DOES 1-60,

DEFENDANTS

The deposition of SCOTT A. GUELCHER, Ph.D.,
called by the Defendants for examination, taken
before Michelle E. Kerr, RPR, a Notary Public in and
for the Commonwealth of Kentucky, Daviess County, at
1719 West End Avenue, Nashville, Tennessee, on
December 18, 2014, commencing at 9:40 a.m.

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A P P E A R A N C E S

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SCOTT A. GUELCHER, Ph.D.,

HAVING FIRST BEEN DULY SWORN TO TELL THE TRUTH, THE
WHOLE TRUTH, AND NOTHING BUT THE TRUTH, TESTIFIED AS
FOLLOWS:

DIRECT EXAMINATION

BY MR. SNELL:

Q State your name for the record, sir.

A Scott Guelcher.

Q What profession are you in, Dr. Guelcher?

A I'm an Associate Professor of Chemical
Engineering at Vanderbilt University.

Q You understand we're here today to take your
deposition in the Coleen Perry case, which is
currently pending in California?

A I do.

Q And you're here today to give your opinions
and the bases for those opinions, correct?

A Yes.

Q When were you first contacted to serve as an
expert in the Perry case?

A I believe it was September, September '14.

Q So in September of 2014, you were contacted
to be an expert in the Perry case?

A That's what I remember.

Q Who were you contacted by?

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A By plaintiff's counsel, Jeff Kuntz and Tom
Cartmell.

Q And what did you understand your assignment
to be in relation to the Coleen Perry case?

A Assignment, I'm not sure what you mean by
that.

Q What did you understand your purpose was to
be as an expert involved in the Perry case?

A Well, I was testifying about defects in the
Abbrevio mesh.

Q Did you say effects?

A Defects in the Abbrevio mesh product.

Q You have given other deposition and trial
testimony in mesh litigation, correct?

A Yes, I have.

Q You testified in the Huskey case that
involved Ethicon's TVT-O product, correct?

A I did.

Q You were deposed and gave trial in West
Virginia, correct?

A That's correct.

Q And at the time that you gave that testimony,
it was under oath as well, correct?

A That's correct.

Q And did you tell the truth in that testimony?

2 (Pages 2 to 5)

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<p>1 A Yes.</p> <p>2 Q How many hours have you spent on the Perry</p> <p>3 case?</p> <p>4 A I'm not sure. I haven't billed any invoices</p> <p>5 for time yet, so I don't know the total</p> <p>6 number of hours.</p> <p>7 Q Can you give me your best estimate?</p> <p>8 A I don't know. Maybe 20. But when I submit</p> <p>9 my invoices, that will be the more reliable</p> <p>10 number. I haven't added it up yet.</p> <p>11 Q Well, do you have the invoices on your</p> <p>12 calendar?</p> <p>13 A No.</p> <p>14 Q In the Huskey case, you testified that you</p> <p>15 submitted your invoices to Dr. Dunn in</p> <p>16 connection with that matter. Do you recall</p> <p>17 giving that testimony?</p> <p>18 A That's correct.</p> <p>19 Q Are you submitting your invoices to Dr. Dunn</p> <p>20 in the Perry case?</p> <p>21 A I'm not sure yet how that will be. I'll be</p> <p>22 billing -- my plan is -- it's not resolved</p> <p>23 yet, whether I will independently or through</p> <p>24 Dr. Dunn's company.</p> <p>25 Q How do you track your time that you spend in</p>	<p>1 Huskey case. Do you recall giving that</p> <p>2 testimony?</p> <p>3 MR. KUNTZ: Objection.</p> <p>4 A I'm not sure what you mean by a cut.</p> <p>5 BY MR. SNELL:</p> <p>6 Q In the Huskey case, as I recall it, you</p> <p>7 received \$200 per hour for review and work,</p> <p>8 correct?</p> <p>9 A I don't believe that's -- well, it was 200 or</p> <p>10 210. He raised the rates. Okay. It was 200</p> <p>11 or 210. The rates have been changed, and I</p> <p>12 don't remember if it was before or after</p> <p>13 Huskey. It may have been 200. It may have</p> <p>14 been 210. I can't remember.</p> <p>15 Q And Dr. Dunn billed \$275 an hour for your</p> <p>16 review time, correct?</p> <p>17 A If I bill 200, then Dr. Dunn would have</p> <p>18 billed 275.</p> <p>19 Q And is it your testimony that that</p> <p>20 arrangement has changed within the last one</p> <p>21 to two months?</p> <p>22 A Yes. I have not submitted any invoices for</p> <p>23 this case, but the plan for moving forward is</p> <p>24 for me to submit invoices independent of</p> <p>25 Dr. Dunn's company.</p>
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<p>1 the Perry case?</p> <p>2 A I have some paper records, but it's not --</p> <p>3 nothing is official. I've not been</p> <p>4 releasing -- in the past, all the invoices</p> <p>5 have been submitted through Dr. Dunn's</p> <p>6 company. Nothing is official until I submit</p> <p>7 the invoices. I don't have the invoices</p> <p>8 right now.</p> <p>9 Q Well, in the Huskey case, you testified under</p> <p>10 oath that you submitted monthly invoices to</p> <p>11 Dr. Dunn, which included the time spent, the</p> <p>12 time of day spent and a brief description of</p> <p>13 your activities. Do you recall giving that</p> <p>14 testimony?</p> <p>15 A I do.</p> <p>16 Q And at what point in time has that changed?</p> <p>17 A Very recently. In the past maybe month or</p> <p>18 two.</p> <p>19 Q When was the last time you sent an invoice to</p> <p>20 Dr. Dunn with regard to your work as an</p> <p>21 expert in mesh litigation?</p> <p>22 A I don't remember. Maybe a month or two ago.</p> <p>23 I don't remember the date.</p> <p>24 Q As I understand it, Dr. Dunn received a cut</p> <p>25 from the amount billed for your work in the</p>	<p>1 Q Do you have your own company that you will be</p> <p>2 submitting invoices under?</p> <p>3 A I do.</p> <p>4 Q What's the name of that company?</p> <p>5 A Guelcher Consulting, LLC.</p> <p>6 Q In the Huskey matter, you testified that you</p> <p>7 kept a calendar and a recording of your time</p> <p>8 spent and the days that you worked as an</p> <p>9 expert. Do you recall giving that testimony?</p> <p>10 A I do.</p> <p>11 Q Have you done the same thing here?</p> <p>12 A I have not. Not in the same way.</p> <p>13 Q Why not?</p> <p>14 A I just changed it. I have a right to change</p> <p>15 the way I keep the time.</p> <p>16 Q So what materials or documents do you have</p> <p>17 that would reflect the time you've spent up</p> <p>18 until the time of this deposition for the</p> <p>19 Perry case?</p> <p>20 A I don't have them yet because I haven't</p> <p>21 submitted the invoices. That's what I said.</p> <p>22 Q I'm not asking about invoices.</p> <p>23 I'm asking what other materials or</p> <p>24 documents -- what would you look to to draft</p> <p>25 an invoice so that you would know the</p>

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<p>1 accurate amount of hours for your billing 2 that you would submit? 3 A I have some paper at home. 4 Q What paper at home? 5 A Well, I have a piece of paper that has hours 6 written on it, but I haven't added everything 7 up yet because I haven't submitted the 8 invoice. 9 Q Is this a piece of paper in a notebook or -- 10 A No, it's just a note. 11 Q Do you have a copy of that that you can give 12 to counsel? 13 A No, I don't, because we haven't been doing 14 that. We've been providing invoices, and 15 Dr. Dunn was providing invoices, and I just 16 don't have an invoice yet that I've sent in. 17 Until it's finalized, I don't -- I've not 18 been submitting records of time until there 19 is a final invoice. 20 MR. SNELL: Well, I'm going to 21 make a request that you get a copy of that to 22 counsel, and we'll attach it to the 23 deposition. 24 MR. KUNTZ: We'll get you a 25 copy.</p>	<p>1 Q For over a year, you submitted invoices 2 through Dr. Dunn and his company, correct? 3 A That's correct. 4 Q Is it your testimony that there was nothing 5 that made you decide to go out and become 6 independent of Dr. Dunn? 7 A Well, that's not what you asked me the first 8 time. You ask me what happened, implying 9 that something disruptive happened in our 10 working relationship, which nothing happened. 11 It's just a decision to do this 12 independently. 13 Q How much are you billing now for your work -- 14 A The same rate. 15 Q Let me finish my question. 16 A Sure. 17 Q How much are you billing for your time as an 18 expert in the Perry case for review of 19 materials? 20 A The same rates as Dr. Dunn. 21 Q Can you tell me how much per hour? 22 A Dr. Dunn raised his rates from 275 to 285 for 23 report writing, reviewing of documents, etc. 24 I will be charging that rate. For testimony, 25 I just can't remember the number right now.</p>
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<p>1 A I can send an invoice after today and that 2 will make it official. Is that okay? 3 BY MR. SNELL: 4 Q Well, that's fine. But I'd like to know what 5 it is because I will have questions about 6 that potentially. 7 A What is? I don't understand. You said you'd 8 like to know what it is if I send you an 9 invoice. You know what it is. It's an 10 invoice that says my hours and what I did, so 11 I'm not sure what you're looking for. 12 Q Well, right now you currently have -- you 13 testified you have a document that has your 14 hours and the time you spent. That's the 15 document I would like. If you draft an 16 invoice, I would like that as well. 17 A Okay. 18 Q When did you form Guelcher Consulting, LLC? 19 A It's been very recent. In the past few weeks 20 maybe. 21 Q What happened between you and Dr. Dunn that 22 led you to believe that you should go out 23 independent of Dr. Dunn? 24 A Nothing happened with Dr. Dunn. I'm not sure 25 what you're asking me.</p>	<p>1 I think it's maybe 385 is a number for 2 testimony, but that would be on the invoice. 3 I can't remember the number right now. 4 Q So it's your intention to bill \$285 per hour 5 for reviewing materials and report writing 6 and things like that? 7 A That's what Dr. Dunn was billing. And since 8 I'm doing the same activities, I thought it 9 reasonable to bill the same rate. 10 Q Dr. Dunn is not an expert in this case. 11 You're aware of that, correct? 12 A My understanding is that Dr. Dunn has not 13 been produced as an expert witness for 14 Plaintiffs. 15 Q All right. So for you -- I just want to get 16 a clean answer without injecting Dr. Dunn 17 into this Q and A. The rates that you, 18 Dr. Guelcher, are charging for report writing 19 and review of documents for this matter in 20 the Perry case will be \$285 per hour; is that 21 correct? 22 A That's correct. 23 Q The rate that you will charge for testimony, 24 as best as you can figure at this point in 25 time, is \$385 per hour?</p>

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<p>1 A That's correct.</p> <p>2 Q Will you have a different rate for trial</p> <p>3 testimony if you are called to testify at</p> <p>4 trial?</p> <p>5 A I don't believe so. I intend to use the same</p> <p>6 rates that were being billed in the past, and</p> <p>7 there was no difference between trial and</p> <p>8 deposition testimony. Those numbers were the</p> <p>9 same. So whatever those numbers are, it will</p> <p>10 be the same. There won't be a difference.</p> <p>11 Q You understand that this trial will be in</p> <p>12 California?</p> <p>13 A Yes.</p> <p>14 Q And you're agreeable to traveling to</p> <p>15 California for trial?</p> <p>16 A Yes.</p> <p>17 Q Your expenses of traveling to California,</p> <p>18 would you bill for those?</p> <p>19 A That's what Dr. Dunn has done in the past,</p> <p>20 and I would continue that practice.</p> <p>21 Q So if you come to trial in California, you</p> <p>22 will bill for your expenses, such as air</p> <p>23 fare, and hotel room, and meals, correct?</p> <p>24 A Yes, that's correct.</p> <p>25 Q Have you ever met Mrs. Perry?</p>	<p>1 have you ever spoken to him?</p> <p>2 A No.</p> <p>3 Q Okay. Dr. Donald Marks, he is another</p> <p>4 expert --</p> <p>5 A I have not.</p> <p>6 Q You have not spoken with him?</p> <p>7 A No.</p> <p>8 Q Have you reviewed any expert reports or</p> <p>9 expert declarations in the Perry case?</p> <p>10 A Yes.</p> <p>11 MR. KUNTZ: Aside from this own?</p> <p>12 MR. SNELL: Yes, of course.</p> <p>13 BY MR. SNELL:</p> <p>14 Q Let me just take that off the table and</p> <p>15 reformulate.</p> <p>16 Setting aside your expert declaration</p> <p>17 listed opinions, have you reviewed any other</p> <p>18 experts' declarations or listed opinions?</p> <p>19 A Declarations, no, I don't believe so.</p> <p>20 Q Okay. For your opinions in this case, you're</p> <p>21 not relying on the declarations or reports of</p> <p>22 any other experts, correct?</p> <p>23 A No, I'm not relying on any other</p> <p>24 declarations.</p> <p>25 Q You're not relying on any other experts'</p>
Page 15	Page 17
<p>1 A I have not.</p> <p>2 Q Have you spoken to Mrs. Perry?</p> <p>3 A I have not.</p> <p>4 Q Have you ever spoken to any of Mrs. Perry's</p> <p>5 family or friends?</p> <p>6 A No.</p> <p>7 Q Have you ever spoken with any of Mrs. Perry's</p> <p>8 doctors?</p> <p>9 A No.</p> <p>10 Q Okay. Have you spoken with any other experts</p> <p>11 about the Perry case?</p> <p>12 A Any other experts defined as --</p> <p>13 Q Defined as -- let me ask you this. Besides</p> <p>14 yourself, who do you understand to be the</p> <p>15 other experts besides yourself in the Perry</p> <p>16 case?</p> <p>17 A I don't know who the other experts are that</p> <p>18 they are calling. I haven't spoken with</p> <p>19 them.</p> <p>20 Q So you have not spoken with a Dr. Rosenzweig</p> <p>21 about the Perry case?</p> <p>22 A I have not.</p> <p>23 Q Have you ever spoken with Dr. Rosenzweig?</p> <p>24 A I have not.</p> <p>25 Q Dr. Michael Thomas Margolis from California,</p>	<p>1 opinions, correct?</p> <p>2 A Yes.</p> <p>3 Q Do you know if any independent medical</p> <p>4 examinations have been done on Mrs. Perry?</p> <p>5 A I'm not aware of any of those outcomes of</p> <p>6 those medical examinations. I've not</p> <p>7 reviewed that.</p> <p>8 Q So you haven't reviewed any of the IME</p> <p>9 outcomes or reports in this Perry case,</p> <p>10 correct?</p> <p>11 A No.</p> <p>12 Q I'm not correct?</p> <p>13 A I have not reviewed, yeah. I'm sorry.</p> <p>14 Q Okay. And you're not relying on the outcomes</p> <p>15 of any IME reports; is that correct?</p> <p>16 A Yes, that's correct.</p> <p>17 Q When you do issue your invoices or invoice</p> <p>18 for the Perry case, will the check be made</p> <p>19 payable to Guelcher Consulting, LLC, or to</p> <p>20 you personally?</p> <p>21 A It will be made to the LLC. I'm the sole</p> <p>22 owner of the LLC, so it will be made to the</p> <p>23 LLC.</p> <p>24 Q Is Guelcher Consulting, LLC, a Tennessee</p> <p>25 corporation?</p>

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<p>1 A Yes. It's been registered with the secretary 2 of state. 3 Q As I understand it from your testimony at 4 Huskey and other matters, you believe your 5 expertise is in the field of biomaterials 6 design? 7 A That's one way of saying it. I have 8 expertise in biomaterials science and 9 engineering. Another way you could say it is 10 that my work involves design of materials for 11 use as bone grafts or skin grafts, design of 12 biomaterials as diagnostics for studying 13 cancer metastasis. 14 Q You have a Ph.D., correct? 15 A Yes. 16 Q Any higher education than that? 17 A I did a postdoctoral research training at 18 Carnegie Mellon in biomedical engineering. 19 Q But that was not something for which a degree 20 was earned; is that correct? 21 A It's not a degree, but it's postdoctoral 22 training. It counts as training. 23 Q You're not a medical doctor, correct? 24 A No, I'm not a medical doctor. 25 Q You're not a pathologist?</p>	<p>1 course on polymer science and engineering at 2 Vanderbilt. 3 Q In prior cases, as I understand it, and have 4 read your testimony, Dr. Dunn, if testing was 5 done, he would have been the one to perform 6 the testing on meshes? 7 A That's correct, Dr. Dunn did the testing. 8 Q Is there a certain reason for that? 9 A The reason relates to the nature of our 10 employments at Vanderbilt. Dr. Dunn is a 11 professor of the practice. I'm a tenured 12 associate professor with a federally-funded 13 research program. And so we have different 14 appointments, that's the reason. 15 Q I don't understand that. 16 Can only professors do the type of 17 testing that he performed in the prior cases? 18 A I'm qualified to do the testing. It's that I 19 have graduate students working in my 20 laboratory on federal research grants. 21 Dr. Dunn has a company with employees. It's 22 simpler for him to do the testing than for me 23 from an administrative perspective. So that 24 doesn't have anything to do with 25 qualifications or ability. It's more because</p>
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<p>1 A I'm not a pathologist. 2 Q You don't treat any patients, correct? 3 A I don't treat patients. 4 Q You're not a toxicologist, correct? 5 A I'm not a toxicologist. 6 Q What is the difference between your expertise 7 and Dr. Dunn's expertise? 8 A So Dr. Dunn and I have overlapping expertise 9 in polymer science and engineering. My 10 expertise is differentiated from Dr. Dunn's 11 in biomaterials, preclinical testing of 12 biomaterials, evaluation of biomaterials 13 using in vitro and in vivo models. Those 14 would be some examples of how my expertise is 15 differentiated from Dr. Dunn's. 16 Q Is Dr. Dunn more of a polymer chemist than 17 you are? 18 A I would not state it this way. I've had 19 extensive experience in polymer chemistry, 20 science and engineering. I've worked for 21 several companies in the area of polymers. 22 My postdoctoral training was in polymers for 23 bone scaffolds. And for the past ten years 24 at Vanderbilt, I've been working on polymers 25 and I taught -- and I developed and taught a</p>	<p>1 of these practical reasons. 2 Q So you have graduate students working under 3 you who are being subsidized, whose work is 4 being subsidized by federal funding; is that 5 correct? 6 A I wouldn't say it's being subsidized. The 7 work is being funded by federal funding, and 8 in some cases, by corporate funding. Their 9 stipends are paid either from fellowships or 10 from the grants, not from the consulting. 11 Q Okay. Well, what about the fact of graduate 12 students working under you who are supported 13 by federal funding, what affect does that 14 have on why Dr. Dunn did the testing and you 15 didn't? 16 A Well, to have graduate students working on 17 that sort of testing would require a 18 disclosure to the university, so I haven't 19 had them involved. I've disclosed the 20 consulting activity to the university 21 required by the policy, but to have graduate 22 students involved would require more, and I 23 just haven't done that at this time. 24 Q What type of disclosure did you make to the 25 university with regard to your goal as an</p>

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<p>1 expert witness?</p> <p>2 A Every year we are required to file a</p> <p>3 disclosure report that would include --</p> <p>4 because I have NIH grants, the NIH requires</p> <p>5 us to disclose travel funded by third</p> <p>6 parties. I'm required to disclose</p> <p>7 relationships with companies that I have had</p> <p>8 grants from companies in the past, consulting</p> <p>9 relationships with companies. These</p> <p>10 activities are disclosed.</p> <p>11 In the past what I've disclosed is that I</p> <p>12 was a consultant working for Polymer and</p> <p>13 Chemical Technologies.</p> <p>14 Q So your disclosure stated that you worked as</p> <p>15 a consultant in polymer and --</p> <p>16 A For Polymer and Chemical Technologies.</p> <p>17 That's Dr. Dunn's company. So last year's</p> <p>18 disclosure, that's what I have filed. I have</p> <p>19 to update it this year again.</p> <p>20 Q Did you identify in your disclosure that you</p> <p>21 were serving as an expert on behalf of</p> <p>22 plaintiffs in the transvaginal mesh</p> <p>23 litigation?</p> <p>24 A We're not required to disclose the activity,</p> <p>25 only the fact that we're consulting.</p>	<p>1 A That's a complex question. It depends on</p> <p>2 what's being used and the specific faculty</p> <p>3 member. It would have to be discussed with</p> <p>4 the university. I don't know the answer to</p> <p>5 that. There is not a fixed answer to that</p> <p>6 question.</p> <p>7 Q If you have one of your graduate students who</p> <p>8 is supported by federal funding analyze</p> <p>9 meshes from the mesh litigation, would you</p> <p>10 have to disclose that to anyone?</p> <p>11 A I would discuss that with the dean's office.</p> <p>12 But Dr. Dunn's company did the testing, so --</p> <p>13 Q Where is Dr. Dunn's company located at?</p> <p>14 A At his residence in Nashville.</p> <p>15 Q He has employees working out of his home in</p> <p>16 Nashville?</p> <p>17 A I can't speak to those details about</p> <p>18 Dr. Dunn's company. I don't know how he</p> <p>19 operates his company other than his business</p> <p>20 relationship with me.</p> <p>21 Q Do you know if Dr. Dunn utilized any of the</p> <p>22 graduate students at Vanderbilt in any</p> <p>23 analyses pertaining to transvaginal mesh?</p> <p>24 A Not to my knowledge.</p> <p>25 Q Do you know if Dr. Dunn utilized any</p>
Page 23	Page 25
<p>1 Q So you did not disclose that you were</p> <p>2 consulting with plaintiffs' attorneys in</p> <p>3 transvaginal mesh litigation?</p> <p>4 A I don't remember what I disclosed right now,</p> <p>5 the exact details. I disclosed that I had a</p> <p>6 consulting relationship. I don't remember</p> <p>7 the detail of what I exactly disclosed. I</p> <p>8 would have to look at it again.</p> <p>9 Q Now, that you're billing your services</p> <p>10 directly through your own corporation, are</p> <p>11 you going to disclose that you are consulting</p> <p>12 and serving as an expert to plaintiffs in</p> <p>13 transvaginal mesh litigation?</p> <p>14 A When I submit the invoices, I will update the</p> <p>15 disclosure, but that hasn't been finalized</p> <p>16 yet. When I submit the invoices, I will</p> <p>17 update the disclosure.</p> <p>18 Q Where does this disclosure get submitted to</p> <p>19 within Vanderbilt?</p> <p>20 A At the dean's office, dean of engineering.</p> <p>21 Q If you do any testing of meshes in your role</p> <p>22 as a plaintiff's expert, and you utilize any</p> <p>23 of Vanderbilt's equipment, personnel, or any</p> <p>24 other assets owned by Vanderbilt, do you have</p> <p>25 to give prior notice of that to Vanderbilt?</p>	<p>1 Vanderbilt personnel besides yourself in any</p> <p>2 analyses or investigation pertaining to</p> <p>3 transvaginal mesh?</p> <p>4 A Again, Dr. Dunn would have to speak to that.</p> <p>5 I don't know.</p> <p>6 Q Who is your immediate supervisor currently?</p> <p>7 A My department chair, Kane Jennings.</p> <p>8 Q Could you spell that?</p> <p>9 A K-A-N-E Jennings.</p> <p>10 Q And that's within the department of what?</p> <p>11 A Chemical and biomolecular engineering.</p> <p>12 Q So you work within the Department of Chemical</p> <p>13 and Biomolecular Engineering at Vanderbilt?</p> <p>14 A That is correct.</p> <p>15 Q Is that a particular school at Vanderbilt?</p> <p>16 A That department is within the school of</p> <p>17 engineering.</p> <p>18 Q Besides Dr. Dunn, who, if anyone else at</p> <p>19 Vanderbilt is aware that you are serving as</p> <p>20 an expert for plaintiffs in the transvaginal</p> <p>21 mesh litigation?</p> <p>22 A Professor Ken Debelak, D-E-B-E-L-A-K. He's</p> <p>23 an Associate Professor of Chemical and</p> <p>24 Biomolecular Engineering at Vanderbilt.</p> <p>25 Dr. Dunn retained him through his company as</p>

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<p>1 an expert in prior litigation over a year 2 ago. I believe Dr. Debelak was deposed in 3 this first case, but not since. 4 Q Have you had anyone at Vanderbilt perform any 5 activity on your behalf with regard to 6 anything you've done in the transvaginal mesh 7 litigation as an expert? 8 A So I have a graduate student who was doing 9 oxidative degradation testing through her 10 dissertation project, and she provided -- 11 well, I asked my graduate students to write 12 standard operating procedures for everything 13 we do. I review and discuss those procedures 14 with them and approve them, and she gave that 15 protocol to Professor Dunn. 16 Q What's the name of this graduate student? 17 A Anne Talley, T-A-L-L-E-Y. 18 Q Let me see if I understand this. So you 19 asked all of your graduate students to write 20 SOP's? 21 A So for anything that we do in the laboratory, 22 for any polymer that we make, for any 23 analysis that we run, such as oxidative 24 degradation testing, we review the literature 25 and prepare a standard operating procedure or</p>	<p>1 solution of 20 percent hydrogen peroxide with 2 cobalt chloride, and I don't remember the 3 exact amount. That's the solution. 4 Q And this solution is used for the in vitro 5 testing of mesh? 6 A This solution was first developed by Dr. Jim 7 Anderson in 1993. It was first published -- 8 his group published a number of papers on it. 9 I published two papers with it. It's used to 10 assess the degradation of biomaterials under 11 oxidative conditions that are similar to 12 those in the human body, more specifically, 13 that are similar to those under conditions 14 where there are adherent inflammatory cells 15 in the biomaterial, the foreign body 16 reaction, I should say, the effects of the 17 foreign body reaction on the stability of the 18 biomaterial. 19 It's a very general well-known 20 established test that's been cited dozens of 21 times. 22 Q So did Ms. Talley or any of your other 23 graduate students do any in vitro testing on 24 the mesh? 25 A No. As I said before, that testing was done</p>
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<p>1 an SOP for the procedure, and I believe 2 that's part of student training. These are 3 the types of activities they will do in the 4 industry, so I ask my students to write these 5 types of documents. 6 Q What did you ask Anne Talley to do 7 specifically that pertained to your work as 8 an expert in the transvaginal mesh 9 litigation? 10 A I didn't ask her -- I asked her to write the 11 SOP for the medium, preparing the medium. 12 And then Dr. Dunn asked her for that SOP is 13 my understanding. 14 Q Why did you ask Ms. Talley to write the SOP 15 for the preparation of the medium? 16 A Well, she was the one that was working in 17 this area on her research project, so she had 18 the most knowledge about it. 19 Q When you say medium, what medium are you 20 referencing? 21 A The medium that was used in the in vitro 22 testing with the mesh. 23 Q What was that medium? 24 A It's a solution of 20 percent cobalt chloride 25 -- I'm sorry. Strike that. It was a</p>	<p>1 by Dr. Dunn's company. 2 Q Was the testing done by Dr. Dunn's company 3 before or after Ms. Talley's SOP was given to 4 Dr. Dunn? 5 A I believe it was after, because they used 6 that SOP to prepare the solution. These 7 activities were done by Dr. Dunn, but I don't 8 know who in his company did what. I just 9 know that my lab through Anne provided them 10 with a solution with a -- strike that -- with 11 an SOP for preparing the solution, and then 12 they did the testing. 13 Q Did Ms. Talley know that she was writing an 14 SOP that would be given to plaintiffs' 15 experts in the transvaginal mesh litigation 16 for utilization in certain testing? 17 A She did not prepare the SOP for plaintiffs. 18 She prepared the SOP for use in my 19 laboratory. She was aware of the mesh 20 litigation, but she was not -- she did not 21 write it for this. It's an SOP for my 22 laboratory. It falls within the scope of her 23 activities on her funded research project. 24 MR. SNELL: Move to strike. 25 BY MR. SNELL:</p>

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Page 30	Page 32
<p>1 Q Did Ms. Talley know that she was preparing an</p> <p>2 SOP that would be given to a plaintiff's</p> <p>3 expert for use in transvaginal mesh</p> <p>4 litigation?</p> <p>5 A The way you asked that question, no, I don't</p> <p>6 believe so. It was written for my</p> <p>7 laboratory. She did not write it for the</p> <p>8 testing. It's an SOP that was in my</p> <p>9 laboratory.</p> <p>10 Q How long did it take Ms. Talley to write this</p> <p>11 SOP?</p> <p>12 A I don't know.</p> <p>13 Q Did you assign Ms. Talley to write this</p> <p>14 particular SOP regarding this testing?</p> <p>15 A I believe so. I asked her to write the SOP</p> <p>16 for the procedure in general to use in our</p> <p>17 lab. We use it for other projects as well.</p> <p>18 Q You were aware when you asked Ms. Talley to</p> <p>19 write the SOP regarding the testing, that it</p> <p>20 would be used by Dr. Dunn in his role as an</p> <p>21 expert for plaintiffs in the mesh litigation?</p> <p>22 A I was aware of that.</p> <p>23 Q Did Dr. Dunn give Ms. Talley any money or</p> <p>24 renumeration for writing this SOP that he</p> <p>25 used in his role as an expert in the mesh</p>	<p>1 this SOP?</p> <p>2 A I don't remember. I don't know when exactly</p> <p>3 she wrote it or when it was revised or</p> <p>4 finalized. I don't remember.</p> <p>5 Q Well, was it this year or last year?</p> <p>6 A I don't know.</p> <p>7 Q When did Dr. Dunn do this testing that he</p> <p>8 utilized Ms. Talley's SOP that she wrote</p> <p>9 while as a graduate student for you?</p> <p>10 A It was done in September.</p> <p>11 Q Of 2014?</p> <p>12 A Yeah.</p> <p>13 Q So, certainly, Ms. Talley would have been</p> <p>14 working on this SOP during the calendar year</p> <p>15 of 2014, correct?</p> <p>16 A She would have been working on it.</p> <p>17 Typically, these are documents that we write</p> <p>18 and we revise, so I have had students write</p> <p>19 SOP's, and then other students come back and</p> <p>20 revise them. That's how we do it. We revise</p> <p>21 them based on new papers that have been</p> <p>22 published, new information, so I don't know</p> <p>23 the history of the document. I can't</p> <p>24 remember that.</p> <p>25 Q Is Ms. Talley currently a graduate student at</p>
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<p>1 litigation?</p> <p>2 A He wouldn't give her renumeration because it</p> <p>3 was written within the course of her work at</p> <p>4 Vanderbilt and her project.</p> <p>5 Q So the answer is, no, he didn't give her any</p> <p>6 money?</p> <p>7 A No.</p> <p>8 Q And did you give Ms. Talley any money or</p> <p>9 renumeration for writing the SOP that you</p> <p>10 were aware of that would be used in testing</p> <p>11 meshes in transvaginal litigation?</p> <p>12 A I didn't give her money because it was</p> <p>13 written for her research project for her work</p> <p>14 at Vanderbilt.</p> <p>15 Q So the answer is no, you didn't give her any</p> <p>16 money, correct?</p> <p>17 A No, but for that reason. It wasn't written</p> <p>18 for the mesh litigation.</p> <p>19 Q Other than Ms. Anne Talley, have you involved</p> <p>20 any of your other graduate students in any</p> <p>21 testing or analyses pertaining to your work</p> <p>22 as an expert in the transvaginal mesh</p> <p>23 litigation?</p> <p>24 A No.</p> <p>25 Q How long ago was it that Ms. Talley wrote</p>	<p>1 Vanderbilt?</p> <p>2 A Yes.</p> <p>3 Q If you had done any of the types of testing</p> <p>4 that Dr. Dunn has performed in his role as an</p> <p>5 expert in the transvaginal mesh litigation on</p> <p>6 the mesh, what type of paperwork or</p> <p>7 disclosures would you have had to give to</p> <p>8 Vanderbilt?</p> <p>9 A I don't know. It's difficult to answer these</p> <p>10 questions. We tend to address them when --</p> <p>11 I just -- as I said earlier, I have not been</p> <p>12 doing testing of materials for litigation at</p> <p>13 Vanderbilt, so I don't know what I would have</p> <p>14 to do. So far I've disclosed the consulting</p> <p>15 activity. I may very well make additional</p> <p>16 disclosures as we move along and the</p> <p>17 situation changes, but it's a very fluid</p> <p>18 situation.</p> <p>19 We disclose these types of things as they</p> <p>20 arise. So it's difficult to say without</p> <p>21 actually seeing the situation.</p> <p>22 Q Does Vanderbilt require you to disclose any</p> <p>23 relationships upon which you receive outside</p> <p>24 monies?</p> <p>25 A I already answered this. We're required to</p>

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<p>1 disclose consulting relationships. When I 2 submit a grant application, I'm required to 3 disclose whether I have a significant 4 financial interest. The NIH changed the 5 rules in 2012. I disclose whether there is a 6 significant financial interest, and then the 7 dean's office works with me to figure out if 8 there is a conflict, and if there is, how do 9 we manage it.</p> <p>10 So there is no fixed set procedure. It's 11 very much handled on a case-by-case basis. 12 And disclosures are continuously updated as 13 new information becomes available.</p> <p>14 Q How is significant financial interest 15 defined?</p> <p>16 A The NIH defines a significant financial 17 interest as \$5,000 a year. That's one way to 18 define it. Another is equity. Strike that. 19 The NIH defines it as \$5,000 or greater. 20 Financial interest, that could be cash. That 21 could be equity. That could be any form of 22 compensation, but the threshold is \$5,000.</p> <p>23 Q Have all monies you receive in your role as 24 an expert in the transvaginal mesh litigation 25 for the calendar year 2014 been paid to you</p>	<p>1 independent role now as an expert and 2 billing as an expert will have on your 3 ability to work or run a lab that has 4 federally-funded research?</p> <p>5 A Yes, I have.</p> <p>6 Q And what affect, if any, have you learned 7 about that?</p> <p>8 A I'm contemplating updating my disclosure. 9 And -- well, I will leave it at that.</p> <p>10 Q Have you had any discussions with anyone at 11 Vanderbilt about ways you could work around 12 the ramifications that the receipt of federal 13 funding has on your role as an expert?</p> <p>14 MR. KUNTZ: Objection.</p> <p>15 A I don't like this word work around. That's 16 not what we do. We identify conflicts. We 17 disclose information to the dean's office. 18 We work with the dean's office to identify 19 conflicts. If conflicts are identified, we 20 work with the dean's office and the general 21 counsel's office to identify and manage a 22 plan, which is then approved -- approved by 23 the conflict of interest committee. 24 I've been through this process multiple 25 times. I've had management plans. I've been</p>
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<p>1 through Dr. Dunn's company?</p> <p>2 A The money I have received has all been 3 received through Dr. Dunn's company, that's 4 right, yes. The money I received, yes.</p> <p>5 Q Does anyone at Vanderbilt know the scope of 6 Dr. Dunn's company?</p> <p>7 A I can't speak to Dr. Dunn's company. I don't 8 know the details of his arrangement with the 9 university. I just don't. He has a 10 different type of appointment than I have. 11 He doesn't do federally-funded research. 12 That's what I know. I don't know the details 13 of his arrangement with Vanderbilt.</p> <p>14 Q Is Dr. Dunn in a position of authority over 15 you at Vanderbilt?</p> <p>16 A No.</p> <p>17 Q If Dr. Dunn wanted to do federally-funded 18 research, would he be able to in light of his 19 activities and the amount of money his 20 company bills for expert work in the 21 transvaginal mesh litigation?</p> <p>22 A I can't speak to that. I don't know how much 23 his company bills or makes. I don't know 24 that information.</p> <p>25 Q Have you investigated what affect your</p>	<p>1 disclosing conflicts to Vanderbilt since I 2 started there. There is a very standard and 3 routine process. Faculty are allowed and 4 encouraged to participate in activities 5 outside of Vanderbilt. I do this in the 6 course of my research with licensing, 7 start-up companies. This is routine.</p> <p>8 There is a process and a procedure. And 9 we're not working around anything. We're 10 trying to find a way to work within the 11 framework of the federal regulations and 12 university policy. It's very standard for 13 universities.</p> <p>14 BY MR. SNELL:</p> <p>15 Q Have you told Vanderbilt how much money you 16 have earned as an expert in the transvaginal 17 mesh litigation?</p> <p>18 A You have asked me this before. And I said we 19 are not required in the course of our work to 20 disclose that. If I believe that I see a 21 conflict between my research and the 22 consulting, then I will disclose that and the 23 university will -- we will have those 24 discussions, but we are not required to 25 disclose this information for consulting</p>

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<p style="text-align: right;">Page 38</p> <p>1 work.</p> <p>2 Q So the answer to my question is, no, you have</p> <p>3 not disclosed that to Vanderbilt, correct?</p> <p>4 A I'm not required -- strike that.</p> <p>5 Q My question is simple. Have you disclosed to</p> <p>6 Vanderbilt --</p> <p>7 A And I believe I have answered your question.</p> <p>8 Q I think you are telling me about what you're</p> <p>9 required to do.</p> <p>10 I'm asking you, have you, Dr. Guelcher,</p> <p>11 disclosed to Vanderbilt the monies, the</p> <p>12 amount of monies you have earned as a</p> <p>13 plaintiff's expert in transvaginal mesh</p> <p>14 litigation?</p> <p>15 MR. KUNTZ: Object. Answer it.</p> <p>16 BY MR. SNELL:</p> <p>17 Q It's a yes or no answer.</p> <p>18 A No, I've not disclosed, but I'm not --</p> <p>19 Q Have you informed your dean of your current</p> <p>20 intention to bill as an independent</p> <p>21 consultant to attorneys in the transvaginal</p> <p>22 mesh litigation?</p> <p>23 A Why would I inform the dean of this? I've</p> <p>24 not informed the dean. I have to inform the</p> <p>25 dean when I believe there is a conflict. And</p>	<p style="text-align: right;">Page 40</p> <p>1 if and when I submit a grant application,</p> <p>2 that would create the conflict, but that's</p> <p>3 tied to INH funding. That's not -- why I'm</p> <p>4 not required to disclose it unless there is a</p> <p>5 conflict of the federally-funded research</p> <p>6 project.</p> <p>7 Q Have you performed any testing on Ms. Perry's</p> <p>8 mesh?</p> <p>9 A I have not.</p> <p>10 Q Have you looked at Ms. Perry's mesh under a</p> <p>11 scanning electron microscope?</p> <p>12 A I have not.</p> <p>13 Q What are all of the different tests, methods</p> <p>14 that one can do to try to determine whether</p> <p>15 there is degradation of polypropylene?</p> <p>16 A So degradation of polypropylene could be</p> <p>17 assessed by SEM imaging. That's typically</p> <p>18 how we assess it.</p> <p>19 Q FTIR --</p> <p>20 A FTIR -- I'm sorry.</p> <p>21 Q FTIR is a way that one can go about trying to</p> <p>22 assess whether there is degradation of</p> <p>23 polypropylene, correct?</p> <p>24 A No, that's not why we use FTIR. We use FTIR</p> <p>25 to assess for oxidation, chemical changes in</p>
<p style="text-align: right;">Page 39</p> <p>1 if and when I make that assessment, I will</p> <p>2 update my disclosure. But according to</p> <p>3 Vanderbilt policy, we're not required to do</p> <p>4 those things.</p> <p>5 Q Well, if you spent approximately 20 hours at</p> <p>6 \$285 an hour thus far, that is over \$5,000.</p> <p>7 Are you telling me that if you have a greater</p> <p>8 than \$5,000 interest in your role as an</p> <p>9 independent billing consultant to</p> <p>10 transvaginal mesh litigation, you do not need</p> <p>11 to tell that to the dean?</p> <p>12 MR. KUNTZ: Objection.</p> <p>13 A No, you are misinterpreting and</p> <p>14 misunderstanding what I have said. The</p> <p>15 question is, whether the proposed research,</p> <p>16 when I submit a grant application, I submit</p> <p>17 an application to the NIH for federal</p> <p>18 funding. I have to answer the question, do</p> <p>19 you have a significant financial interest in</p> <p>20 the outcome of this federally-funded project.</p> <p>21 Significant financial interest is defined</p> <p>22 as more than \$5,000. But at this point in</p> <p>23 time and in the past there -- at this time,</p> <p>24 there is no overlap between the consulting</p> <p>25 work and the federally-funded research. So</p>	<p style="text-align: right;">Page 41</p> <p>1 the polypropylene. That can be assessed by</p> <p>2 the FTIR.</p> <p>3 Q And when you look for oxidation via FTIR,</p> <p>4 what you are looking for is to see if there</p> <p>5 is a potential that would lead to</p> <p>6 degradation; is that correct?</p> <p>7 A No. We are looking at oxidation to answer</p> <p>8 the specific question of is the surface</p> <p>9 oxidizing, is it chemically changing. And we</p> <p>10 can see that by peaks in the FTIR spectra</p> <p>11 that are not there in the normal</p> <p>12 polypropylene, but do appear for oxidized</p> <p>13 polypropylene.</p> <p>14 Q Now, as I understand it, Dr. Dunn, in prior</p> <p>15 work did FTIR in connection with assessing</p> <p>16 the question of is there degradation of</p> <p>17 polypropylene?</p> <p>18 A And why is that -- I don't know what you're</p> <p>19 referring to.</p> <p>20 Q I recall in your Huskey testimony, in your</p> <p>21 deposition, you testified that all of the</p> <p>22 testing done was done by Dr. Dunn. And I</p> <p>23 believe you identified FTIR, XPS, and I don't</p> <p>24 know if there were others.</p> <p>25 A I don't remember the testing that Dr. Dunn</p>

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<p style="text-align: right;">Page 42</p> <p>1 did for the Huskey trial. I do believe we 2 did FTIR. I don't remember the others, but 3 oxidation and degradation are related, but 4 they're -- in terms of -- and there may be 5 times that people use the word degradation to 6 consider all of these effects, but I'm 7 speaking specifically about oxidation as a 8 chemical process, and degradation as a 9 physical one, and they're assessed by 10 different techniques. 11 And I don't remember all of the testing 12 that Dr. Dunn did for the Huskey trial. I 13 don't remember that. 14 Q So if one does FTIR testing and sees that the 15 surface is oxidized, that does not 16 necessarily mean that the material is 17 degraded, correct? 18 A There are different tests to assess -- they 19 could be degraded, but we would assess 20 degradation using a different technique than 21 FTIR. FTIR, as I said, is for chemical 22 oxidation, which is a chemical change. There 23 may be degradation, but we would confirm that 24 with a technique such as SEM. 25 Q So if a scientist has a positive FTIR finding</p>	<p style="text-align: right;">Page 44</p> <p>1 BY MR. SNELL: 2 Q The fact that it's a strong indicator, 3 though, that in and of itself means that 4 there is some possibility that you will not 5 see physical degradation, and there is a 6 possibility as well that you will see it, 7 physical degradation, if you look at SEM, 8 correct? 9 MR. KUNTZ: Objection. 10 A Again, the literature tells us that you would 11 expect degradation. Is it -- unless you 12 actually see it, you can't prove -- you can't 13 guarantee that it's there, but you would 14 certainly expect it. It's within a 15 reasonable degree of scientific certainty to 16 expect that you would have degradation in 17 time if that surface is being oxidized. 18 There are numerous papers that teach 19 about this, about polymers in general, 20 polymers that are susceptible to oxidative 21 attack showed signs of physical degradation. 22 This was all worked out a number of years 23 ago. 24 MR. SNELL: Move to strike. 25 BY MR. SNELL:</p>
<p style="text-align: right;">Page 43</p> <p>1 for oxidation on the surface, he would then 2 need to confirm that with SEM in order to 3 reasonably say with scientific certainty that 4 there was degradation? 5 MR. KUNTZ: Objection. 6 A I would say that the literature teaches us 7 that these processes are related, oxidation. 8 Chemical oxidation leads to physical 9 degradation. And so if I see evidence of 10 oxidation, I would expect to see physical 11 degradation in time. To visibly see that 12 physical degradation, I would do the 13 technique such as SEM. 14 But if I see oxidation, I would certainly 15 expect based on published literature findings 16 that there would be degradation in time to 17 some extent. 18 BY MR. SNELL: 19 Q Well, if you see chemical oxidation, it is 20 not a guarantee that physical degradation has 21 taken place, correct? 22 MR. KUNTZ: Objection. 23 A I think I just answered that. It's a strong 24 indicator that there is also physical 25 degradation.</p>	<p style="text-align: right;">Page 45</p> <p>1 Q My question is this. It's straight forward. 2 The fact that you see chemical oxidation, 3 that does not mean that you would also see 4 under SEM analysis physical degradation if 5 you were to look at that particular time; is 6 that correct? 7 MR. KUNTZ: Objection. Asked 8 and answered. Calls for speculation, and is 9 an incomplete hypothetical. But go ahead. 10 A This is a speculative question. What I'm 11 saying is, if there is oxidative changes, the 12 body of literature teaches within a 13 reasonable degree of scientific certainty 14 that there will be at some time physical 15 degradation. That's what the literature is 16 teaching us. 17 BY MR. SNELL: 18 Q You keep saying at some time there will be 19 physical degradation. At what time will 20 there be physical degradation? 21 A As I've said in my previous testimony, it's 22 unpredictable. And that's a problem for the 23 design of the device, because it's subject to 24 changes that can happen that you can't 25 predict the timing of these changes and what</p>

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<p style="text-align: right;">Page 46</p> <p>1 the implications will be.</p> <p>2 Q Do you have an opinion as to what is the</p> <p>3 earliest point in time where there can be</p> <p>4 physical degradation of Ethicon's Prolene</p> <p>5 polypropylene used in TVT Abbrevio?</p> <p>6 A Again, that's a speculative question. I</p> <p>7 believe that upon implantation, the device</p> <p>8 will be colonized by adherent inflammatory</p> <p>9 cells. This is well-known in the literature,</p> <p>10 the foreign body reaction. Those cells will</p> <p>11 secrete species that oxidize it. The timing</p> <p>12 of all these events can depend on a number of</p> <p>13 factors, the nature of the inflammatory</p> <p>14 response where it's implanted, the mechanical</p> <p>15 stresses in the environment, whether there is</p> <p>16 a bacterial infection.</p> <p>17 The timing can be highly variable. It</p> <p>18 can happen early or it can happen late. The</p> <p>19 point is that it's unpredictable. That's</p> <p>20 what I've been saying.</p> <p>21 Q Well, I would like to know what does the</p> <p>22 literature teach you about the earliest point</p> <p>23 in time when you can say there is physical</p> <p>24 degradation of the Prolene polypropylene</p> <p>25 mesh?</p>	<p style="text-align: right;">Page 48</p> <p>1 time periods of three months and later.</p> <p>2 That's what Clave reported.</p> <p>3 Q And you have a list of materials here today.</p> <p>4 Where in Clave does it say that --</p> <p>5 A I would have to see the paper. I know that</p> <p>6 in Clave, it says that -- he notes that</p> <p>7 explants -- I would have to see it to give a</p> <p>8 precise answer. The number I remember is</p> <p>9 three months.</p> <p>10 (Deposition Exhibit No. 1 was</p> <p>11 marked for identification.)</p> <p>12 BY MR. SNELL:</p> <p>13 Q Doctor, I've handed you Exhibit No. 1. Is</p> <p>14 that the Clave paper you were referring to,</p> <p>15 sir?</p> <p>16 A That is correct.</p> <p>17 Q So can you show me where in Clave it states</p> <p>18 that physical degradation occurred in the</p> <p>19 Prolene polypropylene mesh at a certain time</p> <p>20 period?</p> <p>21 A I'm looking for that. So on Page 264 of</p> <p>22 Clave, it states degradation was observed</p> <p>23 only in samples implanted for at least three</p> <p>24 months.</p> <p>25 Q That is a general statement about the overall</p>
<p style="text-align: right;">Page 47</p> <p>1 I don't want to rehash everything you</p> <p>2 talked about in Huskey. I know you talked</p> <p>3 about what was seen in two years and I</p> <p>4 believe five or seven years in a dog study</p> <p>5 and things like that. So with all of those</p> <p>6 principles that you've already testified</p> <p>7 about, let me just back up and re-ask it.</p> <p>8 A Okay.</p> <p>9 MR. KUNTZ: Objection.</p> <p>10 BY MR. SNELL:</p> <p>11 Q What is the earliest point in time that you</p> <p>12 can say that there is physical degradation of</p> <p>13 the Prolene polypropylene mesh?</p> <p>14 A I just can't answer that question. There are</p> <p>15 too many factors that can influence it. To</p> <p>16 say -- again, it's too speculative. It</p> <p>17 depends on many factors in addition to the</p> <p>18 chemical oxidation.</p> <p>19 Q Based on all of the literature that you saw,</p> <p>20 what was the earliest time reported that</p> <p>21 there was physical degradation of the Prolene</p> <p>22 polypropylene mesh?</p> <p>23 A For Prolene polypropylene, I can say from the</p> <p>24 Clave paper and the explants that were</p> <p>25 studied in Clave, he recorded degradation in</p>	<p style="text-align: right;">Page 49</p> <p>1 cohort of explants, correct?</p> <p>2 A That's my understanding.</p> <p>3 Q That statement is not necessarily particular</p> <p>4 to a Prolene polypropylene mesh implant,</p> <p>5 correct?</p> <p>6 A There could have been Prolene implants in</p> <p>7 this study. That statement doesn't specify</p> <p>8 whether that applies to Prolene or not.</p> <p>9 Q So my question is, can you point to any</p> <p>10 literature which informs you of the earliest</p> <p>11 time which the Prolene polypropylene mesh</p> <p>12 physically degrades?</p> <p>13 MR. KUNTZ: Objection.</p> <p>14 A I don't know of this -- you mean in vivo of</p> <p>15 patients?</p> <p>16 BY MR. SNELL:</p> <p>17 Q Yes, sir.</p> <p>18 A I don't know of a study that has specifically</p> <p>19 reported that.</p> <p>20 Q In the dog study -- and you're still relying</p> <p>21 on the dog study as well with the Prolene</p> <p>22 sutures?</p> <p>23 A The dog study, it's in my reliance materials,</p> <p>24 so it's part of the documents I have</p> <p>25 reviewed.</p>

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<p style="text-align: right;">Page 50</p> <p>1 Q At what point in time was physical 2 degradation observed in that study? 3 A I can't remember. I would have to look at 4 the document. 5 Q Okay. At a break, I would like for you to 6 look at that document. And I will have the 7 same question for the vascular graft Prolene 8 suture study, what is the earliest point in 9 that study if at any point in time it showed 10 physical degradation? 11 A Again, I would have to look at it. I don't 12 remember that level of detail. 13 Q Am I correct that although Clave reports 14 there were 100 explanted samples, a smaller 15 number were actually analyzed? 16 A What do you mean analyzed? I'm not sure what 17 you mean. 18 Q Let me ask you, how many explants were 19 analyzed in the Clave study? 20 A I would have to look at it. There were 100 21 explants. I'm still not sure what you're 22 asking, though. I mean, there were 100 23 explants. 24 Q How many of those 100 explants were actually 25 analyzed?</p>	<p style="text-align: right;">Page 52</p> <p>1 BY MR. SNELL: 2 Q My question was not what is he saying. My 3 question was to you, what limitations does 4 that place upon what one can draw from Clave 5 due to the fact that only 32 out of 100 6 explants were submitted for chemical testing? 7 A I don't see how it limits the finding that he 8 sees changes. That's what he is reporting, 9 whether he sees it in 32 or 50, whether he 10 looked at 32 or 100. I mean, you may be 11 implying that he was cherry-picking data, but 12 I have no reason to believe that. This is a 13 peer-reviewed journal. 14 I mean, he studied what he could study, 15 but it doesn't limit the finding that these 16 changes happened. Whether he did 32 or 100, 17 he still saw changes. So I don't understand 18 how that limits that finding. 19 Q Well, he had 100 explants, and he only 20 subjected 32 to chemical analysis. We can 21 agree to that, right? 22 A That's what he states. But beyond that, I 23 don't -- 24 Q And you don't know the methodology by which 25 he selected the particular 32 for chemical</p>
<p style="text-align: right;">Page 51</p> <p>1 A Well, I think it depends on the method, so -- 2 they did a chemical analysis on 32 explants. 3 It doesn't necessarily say in the methods. 4 Q Why did Clave do less than one-third of the 5 overall sample size for chemical analysis? 6 A I don't know. I would have to look at this 7 to -- 8 Q By only analyzing 32 out of 100 explants for 9 a chemical analysis, what limitations does 10 that place upon the interpretation one can 11 draw from the Clave paper? 12 A Well, what I believe Clave is saying is 13 consistent with my opinions, that these 14 events can happen and can lead to problems 15 and complications. He's not saying it 16 happens all the time in every mesh at this 17 particular time. 18 He is saying that these meshes change, 19 which is consistent, which is my opinion in 20 this case, that the meshes change, and that 21 introduces an extra level of risk because 22 these changes make the meshes -- make their 23 behavior unpredictable. That is what he is 24 saying. 25 MR. SNELL: Move to strike.</p>	<p style="text-align: right;">Page 53</p> <p>1 analysis, correct? 2 A Well, let me read it. I need to read this, 3 because I'm not quite following where you are 4 going with this. 5 Okay. So he says -- I mean, he explains 6 himself. The samples were divided into four 7 groups. Because of the small sample size and 8 physical condition of the explanted 9 materials, extensive and complete chemical 10 analysis was difficult, which I think most 11 would agree is true. And he has several 12 groups listed here, four groups. 13 One of the fourth group is a control with 14 pristine implants, which he has a number of 15 pristine implants listed. So he grouped one 16 as degraded polypropylene that he analyzed by 17 SEM. 18 Group two is a group of nondegraded 19 explants, which again looks like 20 polypropylene mesh. And then the fourth 21 group of PET explants. That's what he says 22 he did. And he says it was difficult. He 23 probably didn't have much material to work 24 with, but these are explants. This isn't a 25 clinical trial. These are explants, so that</p>

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<p style="text-align: right;">Page 54</p> <p>1 is what he had to work with.</p> <p>2 Q But do you know then the methodology by which</p> <p>3 he determined the cut point for whether it</p> <p>4 was too difficult or not to do SEM analysis?</p> <p>5 A He doesn't provide more detail, but this is</p> <p>6 what I understand that he did.</p> <p>7 Q So we have no way of knowing what chemical</p> <p>8 analysis would have shown for those 68</p> <p>9 explants that were not subjected to chemical</p> <p>10 analysis; is that fair?</p> <p>11 A Say that again. I didn't catch it.</p> <p>12 Q Sure.</p> <p>13 We do not know what, if anything, would</p> <p>14 have been shown for the 68 other explants</p> <p>15 that were not subjected to chemical analysis</p> <p>16 because the chemical analyses were not done;</p> <p>17 is that fair?</p> <p>18 A We don't know. He didn't report it, for</p> <p>19 reasons that I'm not entirely sure.</p> <p>20 Q And in Clave's paper, am I correct that not</p> <p>21 all of the polypropylene explants were even</p> <p>22 -- had physical degradation?</p> <p>23 A Yes. But I talked about this earlier, Clave</p> <p>24 is not trying to report the incidents of --</p> <p>25 strike that. He's not trying to report</p>	<p style="text-align: right;">Page 56</p> <p>1 it as, wow, one-third were degraded, that's a</p> <p>2 lot. That's how I look at it.</p> <p>3 Q Regardless of how you want to characterize</p> <p>4 it, let's see if we can agree to this.</p> <p>5 Dr. Guelcher, we can both agree that</p> <p>6 Dr. Clave reported that the rate of</p> <p>7 degradation in the polypropylene monofilament</p> <p>8 was one-third or 33.33 percent, correct?</p> <p>9 A That's what he reported. But to try to</p> <p>10 construe that that is a good number is beyond</p> <p>11 my understanding. That's what he reported.</p> <p>12 He reported that one-third were degraded.</p> <p>13 MR. SNELL: Move to strike. I'm</p> <p>14 just looking for a yes or no.</p> <p>15 BY MR. SNELL:</p> <p>16 Q If we can agree to this basic fact. How you</p> <p>17 characterize it, I know what position you're</p> <p>18 coming from. All right.</p> <p>19 In the Clave paper for the polypropylene</p> <p>20 monofilament, the rate of degradation seen</p> <p>21 was one out of three or 33.33 percent,</p> <p>22 correct?</p> <p>23 A That's what's in the table.</p> <p>24 Q Fair enough.</p> <p>25 And you have your interpretation of that?</p>
<p style="text-align: right;">Page 55</p> <p>1 frequency. He is saying that he observed it.</p> <p>2 With what he had, with what he could test, he</p> <p>3 observed evidence. He doesn't say he</p> <p>4 observed it in every sample, but he did</p> <p>5 observe it. That's what he is saying. So he</p> <p>6 did not observe it in every sample, but we've</p> <p>7 talked about this.</p> <p>8 Q Dr. Clave did report the rate of degradation</p> <p>9 that he saw in the samples that he actually</p> <p>10 did analyze, correct?</p> <p>11 A He did report that number but --</p> <p>12 Q So for polypropylene monofilament at the</p> <p>13 table at the top of Page 266, do you see</p> <p>14 that?</p> <p>15 A I see that number. I know what you're</p> <p>16 saying.</p> <p>17 Q And you understand the Prolene polypropylene</p> <p>18 mesh in the TVT Abbrevio to be a monofilament</p> <p>19 polypropylene?</p> <p>20 A Yes.</p> <p>21 Q And what Clave found was that only one-third</p> <p>22 of that sample of polypropylene monofilament</p> <p>23 that he actually looked at was degraded,</p> <p>24 correct?</p> <p>25 A I look at it a little differently. I look at</p>	<p style="text-align: right;">Page 57</p> <p>1 A I do.</p> <p>2 Q And let me ask you, if more likely than not</p> <p>3 it's 51 percent or higher, you can't look at</p> <p>4 the Clave paper and say it's more likely than</p> <p>5 not that there would be degradation to</p> <p>6 polypropylene monofilament mesh, correct?</p> <p>7 MR. KUNTZ: Objection. You can</p> <p>8 answer.</p> <p>9 A If I were a patient looking at that number, I</p> <p>10 would be concerned.</p> <p>11 MR. SNELL: Move to strike.</p> <p>12 Nonresponsive.</p> <p>13 BY MR. SNELL:</p> <p>14 Q When you look the Clave paper, you can't say</p> <p>15 it's more likely than not that there was</p> <p>16 degradation to the polypropylene monofilament</p> <p>17 mesh, correct?</p> <p>18 MR. KUNTZ: Objection.</p> <p>19 A I don't even know how to answer that</p> <p>20 question. I mean, it's -- he reported 33</p> <p>21 percent. I will agree that he reported that</p> <p>22 in this table, in table two, he reports -- or</p> <p>23 figure two, he reports that 33 percent were</p> <p>24 degraded. Beyond that, I can't -- that's</p> <p>25 what he says.</p>

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<p style="text-align: right;">Page 58</p> <p>1 BY MR. SNELL:</p> <p>2 Q So you would agree that Dr. Clave's paper in</p> <p>3 this table and report, that it's more likely</p> <p>4 than not that the mesh was actually not found</p> <p>5 to be degraded, correct?</p> <p>6 A I cannot answer that question. That doesn't</p> <p>7 make any sense. I mean, this is what he</p> <p>8 reported. To try to construe that -- that's</p> <p>9 what he reported and what he tested. To try</p> <p>10 to construe more out of this, this wasn't a</p> <p>11 controlled study where he was trying to</p> <p>12 measure rate of degradation. He made</p> <p>13 observations and he reported a number, this</p> <p>14 percentage that I saw to be degraded.</p> <p>15 He was not aiming to estimate some -- he</p> <p>16 is just reporting. This is the way I read</p> <p>17 this paper. So I can't answer this question</p> <p>18 that it's more likely than not on anything.</p> <p>19 That's just the number he provides.</p> <p>20 Q So the Clave paper we can agree does not</p> <p>21 stand for the proposition that it's more</p> <p>22 likely than not that polypropylene</p> <p>23 monofilament is degraded?</p> <p>24 MR. KUNTZ: Objection.</p> <p>25 A I can't agree to this line of questioning.</p>	<p style="text-align: right;">Page 60</p> <p>1 That's what I'm saying. Unpredictable means</p> <p>2 you can't predict, and that's a problem.</p> <p>3 That's why the design is flawed is because</p> <p>4 you can't predict. The changes can happen,</p> <p>5 and you can't predict when or the</p> <p>6 implications of those changes.</p> <p>7 My simple point is that Clave sees those</p> <p>8 events and reports them, but this is not a</p> <p>9 study designed to investigate the number of</p> <p>10 meshes that got -- that were degraded.</p> <p>11 That's not what he is saying. He is</p> <p>12 observing -- he is reporting an observation.</p> <p>13 I think you're misinterpreting. You're</p> <p>14 trying to put me in a position to</p> <p>15 misinterpret Clave, and I can't do that. I</p> <p>16 can only report on what I see.</p> <p>17 BY MR. SNELL:</p> <p>18 Q So you can only report that for the samples</p> <p>19 that Clave did decide to analyze for</p> <p>20 degradation, it was 33.33 percent for the</p> <p>21 polypropylene monofilament, and to try to</p> <p>22 take that number and extrapolate it is not</p> <p>23 something you're willing to do?</p> <p>24 MR. KUNTZ: Objection.</p> <p>25 A When have I done that in trial testimony?</p>
<p style="text-align: right;">Page 59</p> <p>1 This is -- why can't we not just agree that</p> <p>2 -- I agree this is what he reported. And</p> <p>3 beyond that, I'm not going to agree to any</p> <p>4 other interpretation of that number. That's</p> <p>5 what he reports. It's an observation saying</p> <p>6 that this can happen, which is what I've been</p> <p>7 saying in my trial and deposition testimony,</p> <p>8 that these events can happen and Clave</p> <p>9 observed it. That's what it says.</p> <p>10 Q So you believe these events of degradation</p> <p>11 can happen, and Clave observed it in</p> <p>12 one-third of the sample, correct?</p> <p>13 A He observed it in 33 percent of the samples</p> <p>14 that he tested.</p> <p>15 Q And an expert can take Clave and say, because</p> <p>16 it was seen in Clave, and it was seen in</p> <p>17 33.33 percent, that means that all meshes</p> <p>18 will be degraded, correct?</p> <p>19 MR. KUNTZ: Objection. Asked</p> <p>20 and answered.</p> <p>21 A But I've not been saying that. I've been</p> <p>22 saying specifically that oxidation and</p> <p>23 degradation can occur in these meshes, and it</p> <p>24 can lead to adverse events. The timing of</p> <p>25 when -- these things are unpredictable.</p>	<p style="text-align: right;">Page 61</p> <p>1 You've seen my depositions.</p> <p>2 MR. SNELL: Move to strike.</p> <p>3 BY MR. SNELL:</p> <p>4 Q We are going to be here all day. I'm not</p> <p>5 asking about when did I see you doing</p> <p>6 something. I'm really not.</p> <p>7 A I just feel like you're covering old ground</p> <p>8 that I've been over so many times, and you're</p> <p>9 trying to get me to misrepresent a paper that</p> <p>10 I've testified about so many times. And I</p> <p>11 don't understand why you're doing that.</p> <p>12 That's why I'm frustrated.</p> <p>13 Q Well, it's a simple yes or no answer.</p> <p>14 A But the questions are convoluted. And the</p> <p>15 way you're asking them is implying certain</p> <p>16 things. When you say he decided to analyze.</p> <p>17 Why could we not say, Clave analyzed -- in</p> <p>18 the number of samples that Clave estimated by</p> <p>19 SEM, he observed 33 percent of them were</p> <p>20 degraded. I agree with that. That's what</p> <p>21 Clave says.</p> <p>22 But I don't want to agree to any other</p> <p>23 questions that infer some kind of intent or</p> <p>24 something in Clave. That's what I'm</p> <p>25 resisting. I'm not trying to be difficult.</p>

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<p style="text-align: right;">Page 62</p> <p>1 I just feel like I have been very clear about 2 what I think about this paper. And I'm just 3 saying that it is consistent with my 4 testimony that these events can happen. 5 That's what I am saying. That's what I have 6 always been saying. 7 Q I just want to get an answer to my question. 8 You interpret Clave as being consistent 9 with your opinion in that it can happen. And 10 Clave observed it in 33.33 percent, correct? 11 A Yes, he observed it in 33 percent, that's 12 fine. 13 Q But you not take Clave and extrapolate Clave 14 to say that a certain rate of degradation 15 will be seen in the mesh samples? Yes or no. 16 MR. KUNTZ: Asked and answered. 17 Eight times. 18 A I've not done that and I'm not doing that 19 now. 20 BY MR. SNELL: 21 Q Okay. That's all I wanted to know was is 22 that something you would do or would not do. 23 A Well, where you ended up with the question, I 24 was fine with it. I'm not trying to be 25 difficult. I'm sorry.</p>	<p style="text-align: right;">Page 64</p> <p>1 there is no case specific depositions on 2 there. 3 MR. SNELL: Well, that is what I 4 was going to say. 5 BY MR. SNELL: 6 Q So, Dr. Guelcher, I looked at your reliance 7 list. It's on the thumb drive. And I didn't 8 see any case specific depositions, 9 particularly from Mrs. Perry's case. Is that 10 consistent or inconsistent with your 11 knowledge? 12 A I have -- it's consistent with my knowledge, 13 yeah. 14 Q You're not relying on any case specific 15 depositions in the Perry case for your 16 opinions are you, sir? 17 A I am not. 18 Q All right. Thank you. 19 A Okay. 20 Q Earlier we were talking about some testing. 21 And you didn't do any SEM testing on 22 Mrs. Perry's explant, correct? 23 A No, I did not. 24 Q Did you have anybody else do any testing of 25 Mrs. Perry's explant on your behalf?</p>
<p style="text-align: right;">Page 63</p> <p>1 MR. SNELL: All right. Let's 2 take a break. 3 (A brief recess was taken from 4 10:40 to 10:50 a.m.) 5 BY MR. SNELL: 6 Q Doctor, you didn't look at Mrs. Perry's 7 medical records, correct? 8 A I did not look at her records. 9 Q Did you look at any of the depositions taken 10 in Mrs. Perry's case, hers or any of her 11 doctors or family members? 12 A I looked at some depositions, but I can't 13 remember exactly those -- I don't know. 14 Q Are you certain that they were depositions in 15 the Perry case or could they have been from 16 some other matter? 17 A It could have been. There has been so many 18 cases, it's hard for me to keep all of the 19 documents straight. 20 Q I'm looking at your reliance list, and I gave 21 you this back. 22 A The reliance list? 23 Q Your list of materials on there that you 24 provided -- 25 MR. KUNTZ: I will tell you that</p>	<p style="text-align: right;">Page 65</p> <p>1 A I did not. 2 Q Okay. You didn't do any FTIR testing on 3 Mrs. Perry's explant, correct? 4 A I did not. 5 Q Did you do any GPC testing on Mrs. Perry's 6 explant? 7 A No. The only explant I received was in the 8 form of sections of the slides of tissue, so 9 it's -- I didn't do any of this type of 10 testing on that material. 11 Q You did not do XPS testing on Mrs. Perry's 12 mesh, correct? 13 A That's correct. 14 Q You did not do DSC testing on Mrs. Perry's 15 mesh, correct? 16 A No. 17 Q You did not do EDX testing on Mrs. Perry's 18 mesh; is that correct? 19 A That's correct. 20 Q Are there any tests besides SEM, FTIR, GPC, 21 XPS, DSC and EDX that someone can do to look 22 for either chemical or structural 23 degradation? 24 A So Dr. Iakovlev, who has testified in other 25 litigation, not in this particular case I</p>

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<p style="text-align: right;">Page 66</p> <p>1 don't believe, but he has a microscopic 2 method for evaluating degradation of the mesh 3 by microscopy. 4 Q Dr. Iakovlev is a pathologist as you 5 understand it? 6 A He is a pathologist at a hospital in Toronto. 7 Q And Dr. Iakovlev is not an expert in this 8 case to your knowledge; is that correct? 9 A To my knowledge. I've not discussed this 10 case with Dr. Iakovlev. 11 Q Do you know if Dr. Iakovlev has looked at 12 Mrs. Perry's mesh or slides? 13 MR. KUNTZ: Objection. 14 A Not to my knowledge. 15 BY MR. SNELL: 16 Q Do you know if Dr. Iakovlev's microscopic 17 method for evaluating mesh has been analyzed 18 by any of the pathology medical societies, 19 like the American Association of Surgical 20 Pathologists or the American College of 21 Pathology? 22 A I don't know the answer to that. But we are 23 preparing a manuscript on explaining mesh 24 that will be submitted soon. And I'm a 25 co-author on that manuscript.</p>	<p style="text-align: right;">Page 68</p> <p>1 manuscript. 2 Q As you sit here today, is it correct, sir, 3 that you do not know the particular patients 4 for whom those slides were made that are 5 going to be the subject of this manuscript? 6 A That is correct. I do not know their 7 identity. 8 Q Okay. Actually, some slides from Mrs. Perry 9 were brought to the deposition today, 10 correct? 11 A That's correct. 12 Q Have you looked at those slides? 13 A I looked at them visually, but I did not look 14 at them under the microscope. 15 Q Okay. Now, the Perry slides that you looked 16 at visually, how did you come to obtain 17 those? 18 A Through plaintiff's counsel. 19 Q You didn't get those through from 20 Dr. Iakovlev? 21 A No, I did not. Plaintiff's counsel. 22 Q And you have not sent Mrs. Perry's slides to 23 Dr. Iakovlev, correct? 24 A I received the slides from Plaintiff's 25 counsel, and they have been in my possession</p>
<p style="text-align: right;">Page 67</p> <p>1 Q Does this manuscript concern Mrs. Perry's 2 explant to your knowledge? 3 A I am not aware of Dr. Iakovlev -- strike 4 that. From my perspective, the patients are 5 de-identified. I don't know the identity of 6 any patients in that study. What 7 Dr. Iakovlev knows, I don't know. 8 Q And were these explanted meshes received by 9 you or Vanderbilt or were they received by 10 Dr. Iakovlev or someone else? 11 A They were all received by Dr. Iakovlev from 12 varying sources. And all of those details, 13 he knows. I did not handle the specific 14 materials. I was never involved in that. 15 Q For this testing, who did the testing that is 16 going to be the subject of this manuscript? 17 A So Dr. Iakovlev did the testing. My 18 contribution was suggesting disdain for 19 myeloperoxidase, which is a marker for 20 reactive oxygen. And that information is 21 concluded and discussed in the manuscript. 22 And I have assisted Dr. Iakovlev with 23 revising and editing the manuscript. 24 I have made my changes and sent these to 25 him. And that's been my role in the</p>	<p style="text-align: right;">Page 69</p> <p>1 since. 2 Q Okay. When did you receive those slides that 3 are particular to Mrs. Perry? 4 A A few weeks ago maybe. I don't remember 5 exactly. 6 Q What is this myeloperoxidase stain that you 7 referenced earlier? 8 A It's myeloperoxidase. It's spelled 9 M-Y-E-L-O-P-E-R-O-X-I-D-A-S-E. 10 Q And what is the purpose of the 11 myeloperoxidase stain? 12 A So myeloperoxidase is an enzyme that converts 13 hydrogen peroxide and other substrates to 14 hydroxyl radicals and other forms of reactive 15 oxygen species. And so if we see a stain 16 that is positive for myeloperoxidase, that 17 tells us that the inflammatory cells are 18 secreting reactive oxygen species, that the 19 mesh is being exposed to the reactive oxygen 20 species and would therefore be a marker of 21 this initiation of events of oxidation and 22 degradation. That's the purpose of the 23 stain. 24 Q Okay. To your knowledge, Mrs. Perry's 25 pathology slides have not been stained with</p>

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<p>1 this myeloperoxidase stain; is that correct?</p> <p>2 A That's my understanding.</p> <p>3 Q So as I understand it, the myeloperoxidase</p> <p>4 stain --</p> <p>5 A You can call it MPO.</p> <p>6 Q Thank you. That makes it a lot easier.</p> <p>7 The MPO stain is a stain that one can do</p> <p>8 to look for reactive oxygen?</p> <p>9 A That's correct. I published two papers on</p> <p>10 this in my work at Vanderbilt. So it's a</p> <p>11 routine essay.</p> <p>12 Q And reactive oxygen is what these</p> <p>13 inflammatory cells secrete or can secrete; is</p> <p>14 that correct?</p> <p>15 A So the Dr. Anderson review that's in my</p> <p>16 reliance materials from the 2008 seminars in</p> <p>17 immunology teaches that within days of</p> <p>18 implantation, the biomaterial, including</p> <p>19 polypropylene, including Prolene mesh, is</p> <p>20 colonized by these inflammatory cells that</p> <p>21 adhere to the surface. And the enzymes that</p> <p>22 they secrete, such as MPO, are these --</p> <p>23 result in the formation of reactive oxygen</p> <p>24 species to which the surface of the material</p> <p>25 is exposed.</p>	<p>1 counsel. So just to clarify your question,</p> <p>2 the slides as I received them to my knowledge</p> <p>3 were not stained for MPO, and so that</p> <p>4 assessment could not be made. It could be</p> <p>5 possible to do that work, but that's a</p> <p>6 decision for the attorneys to work out, not</p> <p>7 me.</p> <p>8 Q All right. To your understanding, it could</p> <p>9 be possible that plaintiff's counsel could</p> <p>10 have those slides stained for MPO, correct?</p> <p>11 A It's a complicated question how these samples</p> <p>12 are handled, whether or not they're in the</p> <p>13 right form that it can be done. I would</p> <p>14 think we would need the blocks to cut new</p> <p>15 slides. I don't know what material is</p> <p>16 available. I would say in theory it could be</p> <p>17 done, but I don't know how practical that is.</p> <p>18 I don't know the history of the slides,</p> <p>19 that's the history of the explants.</p> <p>20 Q You would not be the one looking at the</p> <p>21 slides under the microscope if an MPO stain</p> <p>22 was done in any event?</p> <p>23 A I would. I would look at that under the</p> <p>24 microscope and I would take a picture. My</p> <p>25 students have done that in the past. But</p>
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<p>1 That's what's happening. That's what I</p> <p>2 have testified to in the past.</p> <p>3 Q Okay. We can't say in Mrs. Perry's case that</p> <p>4 there is MPO at the site of her mesh,</p> <p>5 correct?</p> <p>6 A I would say that with a reasonable degree of</p> <p>7 scientific certainty, he's talking about</p> <p>8 Anderson's 2008 paper. Adherent macrophages,</p> <p>9 when they adhere, they become activated, and</p> <p>10 they begin to secrete ROS or reactive oxygen</p> <p>11 species. And the explants that Dr. Iakovlev</p> <p>12 has looked at, he has seen myeloperoxidase</p> <p>13 staining in the ones that he's stained.</p> <p>14 And so from a reasonable degree of</p> <p>15 scientific certainty, I would expect to see</p> <p>16 myeloperoxidase, but we did not -- those</p> <p>17 stains, those slides to my knowledge have not</p> <p>18 been stained for MPO, and so I could not</p> <p>19 assess that.</p> <p>20 Q Is it fair to say you could not assess in the</p> <p>21 Perry case MPO's presence at the mesh; is</p> <p>22 that correct?</p> <p>23 A I don't think I like the words could not.</p> <p>24 They could be stained. This work could be</p> <p>25 done, but that's a decision for plaintiff's</p>	<p>1 this is evidence, I'm not going to just take</p> <p>2 those slides and stain them for MPO not</p> <p>3 knowing their history. There are legal</p> <p>4 ramifications to that. You know, both sides</p> <p>5 have to agree to testing procedures.</p> <p>6 This is a complicated question. All I'm</p> <p>7 saying is that to my knowledge these are H&E</p> <p>8 sections. And to assess the presence of</p> <p>9 myeloperoxidase, they would need to be</p> <p>10 stained.</p> <p>11 Q To assess the presence of MPO, the slides</p> <p>12 would need to be stained?</p> <p>13 A To confirm it. I need to be very clear what</p> <p>14 I'm saying. Based on a reasonable degree of</p> <p>15 scientific certainty, my work with</p> <p>16 Dr. Iakovlev, my reading of the literature, I</p> <p>17 would fully expect to see positive stain from</p> <p>18 myeloperoxidase. That has not been visibly</p> <p>19 confirmed in a section because the slides</p> <p>20 have not stained for that enzyme.</p> <p>21 Q What is the literature that you are</p> <p>22 referencing with regard to your opinion that</p> <p>23 you would expect the MPO stain to be positive</p> <p>24 if it was done in Mrs. Perry's case?</p> <p>25 A The paper that comes to mind would be a</p>

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Scott A. Guelcher, Ph.D.

<p style="text-align: right;">Page 74</p> <p>1 review paper by Professor Jim Anderson at 2 Case Western from 2008 where he cites a very 3 large number of papers in this review. 4 And he teaches that upon implantation, 5 the surface is colonized by these monocytes, 6 inflammatory cells, that differentiate in the 7 macrophages, foreign body giant cells, and 8 become activated when they adhere to that 9 surface and secrete reactive oxygen species, 10 such as myeloperoxidase or they produce. 11 Q This work by Dr. Iakovlev, has it been 12 published anywhere that you have seen, in a 13 peer-reviewed journal? 14 A It's not been published. We're preparing to 15 submit it, the manuscript. It's not been 16 published yet, though. It's still a 17 confidential work product that will be 18 submitted. 19 Q Do you have a copy of the manuscript on the 20 thumb drive? 21 A No. It's a confidential work product with 22 Dr. Iakovlev, so we have to maintain strict 23 confidentiality when we submit to the 24 journals so we don't compromise the review 25 process.</p>	<p style="text-align: right;">Page 76</p> <p>1 Q How large of a cohort is this? 2 A 130 patients, explants from 130 patients. 3 Q And this is a cohort for whom you do not know 4 which patients are particularly involved? 5 A I am blind to patient identity. 6 Q Okay. Would it be fair to say you do not 7 know which manufacturer's meshes are involved 8 for whichever particular patient in that 9 study? 10 A I believe that in the manuscript, 11 Dr. Iakovlev mentions some of the devices, 12 but I don't know which device went in which 13 patient. And I don't know if Dr. Iakovlev 14 has that information. 15 Q As you sit here, you do not personally have 16 knowledge about what device went into which 17 patient? 18 A I do not. 19 Q As you sit here, you do not personally know 20 which particular manufacturer's devices were 21 the subject of the 130 patients? 22 A I believe I have that information. It may be 23 in the manuscript. I just can't remember. I 24 don't remember. That information may be in 25 the manuscript, but certainly I don't know</p>
<p style="text-align: right;">Page 75</p> <p>1 Q Do you know the rate at which the MPO 2 standing was positive in the samples that 3 Dr. Iakovlev did? 4 A When you say rate, I think you mean 5 frequency? 6 Q Sure. 7 A From my understanding, all of the explants 8 that I've seen from Dr. Iakovlev stained 9 positive for myeloperoxidase. So I'm not 10 saying that everything I've seen is positive 11 for myeloperoxidase. 12 Q These are other litigation explants, correct? 13 A In some cases. I have seen explants from 14 Dr. Iakovlev for other litigation, and there 15 is also the manuscript. So I should say, the 16 explants that I've seen stain for 17 myeloperoxidase from Dr. Iakovlev. All have 18 tested positive for myeloperoxidase or MPO. 19 Q Do you have those explants or samples in your 20 possession? 21 A I do not. That's Dr. Iakovlev's work 22 product. I've seen -- Dr. Iakovlev has sent 23 me images, pictures of the slides that I've 24 included in expert reports in previous 25 testimony.</p>	<p style="text-align: right;">Page 77</p> <p>1 which device was with which patient. I would 2 not know that because I don't know the 3 patients. 4 Q You don't have personal knowledge such that 5 you have confirmed that a particular 6 manufacturer's device was the subject of the 7 130-patient study, correct? 8 A Yeah, I can't disclose that right now. I 9 can't even remember it. I'm just saying for 10 the record, it may be in the manuscript, but 11 I don't remember those devices. 12 Q If it may be in the manuscript, it's 13 something that Dr. Iakovlev would have put in 14 there and not you? 15 A Yes, that's fair. 16 Q So you don't have personal knowledge, you've 17 been relying on what Dr. Iakovlev said, if 18 indeed he even said it in the manuscript, 19 correct? 20 A That's correct. 21 Q So I guess you would not know if there were 22 any TVT Abbrevos that were the subject of 23 this manuscript? 24 A I don't remember. But I'm not relying on the 25 manuscript for my opinions in this case,</p>

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<p style="text-align: right;">Page 78</p> <p>1 because it's not been published yet, and 2 we're not disclosing it, so -- 3 Q Okay. 4 A You're asking me about my experience with 5 mesh and I'm telling you. That's my 6 understanding. 7 Q Fair enough. 8 You're not relying on that manuscript in 9 the 130-patient analysis for your opinions in 10 this case, in the Perry case? 11 A Yes, I would say those findings confirm my 12 opinions, but I am not relying on them 13 because that manuscript is still a work in 14 progress. 15 Q So when the inflammatory cell attaches to the 16 mesh or to a foreign body, MPO is one of the 17 substances it can release? 18 A Well, I would say that MPO is an enzyme in 19 the cell that catalyzes the reaction of 20 substrates, such as peroxides, to form, 21 reactive oxygen species such as, you know, 22 hydroxyl radicals, superoxide. There is a 23 very large number of these reactive oxygen 24 species, but MPO is an enzyme that generates 25 those reactive oxygen species.</p>	<p style="text-align: right;">Page 80</p> <p>1 and the properties change very dramatically. 2 But degradation can occur prior to induction, 3 and it certainly can occur after induction, 4 so the two processes are related. 5 The mechanical stresses can certainly 6 impact this as well. That's known as 7 environmental stress cracking. So they are a 8 factor, so you can't separate the two. The 9 mechanical stresses and the chemical stresses 10 are interrelated. 11 Q You've not seen any embrittlement of 12 Mrs. Perry's mesh, correct? 13 A I have not tested for it and have not seen 14 it. 15 Q You've not seen any cracking of Mrs. Perry's 16 mesh, correct? 17 A Correct. I haven't tested for it and seen 18 it. 19 Q You have not seen any molecular weight loss 20 from Mrs. Perry's mesh, correct? 21 A No. I've not tested for that and seen it. 22 Q Besides the macrophages, are there any other 23 cells that you will plan to testify can 24 release these reactive oxygen species? 25 A Well, Dr. Anderson teaches that monocytes,</p>
<p style="text-align: right;">Page 79</p> <p>1 Q It's your opinion that the reactive oxygen 2 species produce compounds, chemicals, which 3 has an affect on the mesh? 4 A So the reactive oxygen species do impact the 5 mesh. They -- through this oxidation 6 chemistry of polypropylene, the tertiary 7 carbon hydrogen bond is subject to attack, 8 and those radicals will attack that bond and 9 oxidize the polypropylene. 10 Q If the radicals don't attack the bond, does 11 the polypropylene get oxidized? 12 A It may be other mechanisms. The most 13 well-known is this radical attack. 14 Q Are you going to come in and testify that 15 there are other methods by which the 16 polypropylene gets degraded besides this, you 17 know, attacking the bond that you've talked 18 about? I don't see it here in your summary 19 of opinions. 20 A So in my summary of opinions, I discussed the 21 interactions between oxidation and 22 degradation. And my point is that oxidation 23 as we're saying is a very early event. It 24 happens immediately upon implantation. And 25 at some point, the materials become induced,</p>	<p style="text-align: right;">Page 81</p> <p>1 which are very small mononuclear cells, 2 colonize the implant, and then those cells -- 3 and they adhere to the implant. And when 4 they attach or adhere to the surface of the 5 implant, they become activated. They can 6 differentiate to become macrophages or 7 macrophages can fuse to form foreign body 8 giant cells. 9 And these cells all come from a common 10 lineage, so they're all inflammatory cells. 11 So when they're adhered, they're activated to 12 secrete ROS. Other types of cells, such as 13 neutrophils, which is commonly seen during 14 acute inflammation or infection, also secrete 15 ROS. So there are other cell populations. 16 Really just many, many types of cells secrete 17 ROS. But in my previous testimony, I was 18 focusing specifically about these adherent 19 macrophages in giant cells. 20 Q It's fair to say you're going to focus on the 21 adherent macrophages in giant cells in the 22 Perry case? 23 A Yes. 24 Q Okay. What happens with the macrophages is 25 -- do they get signaled to the site?</p>

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<p style="text-align: right;">Page 82</p> <p>1 A So the signaling is very complex and it's</p> <p>2 reviewed in Dr. Anderson -- and it's just</p> <p>3 part of the foreign body reaction. When you</p> <p>4 implant a foreign body, many different types</p> <p>5 of cells infiltrate that site of injury, and</p> <p>6 there are various chemical signaling factors</p> <p>7 that are involved. It's just very complex.</p> <p>8 Q Well, let's not go down that road. I was</p> <p>9 trying to get to a simplistic step-by-step</p> <p>10 process.</p> <p>11 So the macrophages are signaled to the</p> <p>12 site of the mesh or wherever there would be a</p> <p>13 foreign body?</p> <p>14 A I would say that monocytes are recruited due</p> <p>15 to the injury, and that mechanism is very</p> <p>16 complex. But they go to the site of injury,</p> <p>17 and they adhere to the foreign body.</p> <p>18 Q Okay. I guess the question I want to ask is,</p> <p>19 monocytes in the foreign body giant cells,</p> <p>20 it's correct that they can persist at the</p> <p>21 site of a foreign body for years, correct?</p> <p>22 A So Dr. Anderson teaches in that review that</p> <p>23 they're present --</p> <p>24 Q Can you answer my question yes or no and then</p> <p>25 the basis after?</p>	<p style="text-align: right;">Page 84</p> <p>1 Academy, and his seminal work is in this area</p> <p>2 of foreign body reaction. And in this paper,</p> <p>3 he is saying that the cells adhere and become</p> <p>4 activated. And I know that there is a fair</p> <p>5 amount of scientific research aimed at this</p> <p>6 idea of inactivating macrophages. I'm aware</p> <p>7 of this.</p> <p>8 But, again, to my knowledge, the teaching</p> <p>9 in the field is that they are activated. The</p> <p>10 work I've done with Dr. Iakovlev is saying</p> <p>11 that when we see these cells, we see</p> <p>12 myeloperoxidase when we stain for it. So</p> <p>13 that's why I'm expressing the opinion with a</p> <p>14 reasonable degree of scientific certainty</p> <p>15 that these cells are activated and secrete</p> <p>16 ROS when they are attached, when they adhere</p> <p>17 to the foreign body.</p> <p>18 Q Did you look for literature that was contrary</p> <p>19 to your opinion that these cells remain</p> <p>20 activated?</p> <p>21 A I'm aware of work in this area just through</p> <p>22 my work that I do. I can't think of a</p> <p>23 specific paper right now. If you have one</p> <p>24 you want me to look at, I can. I'm just</p> <p>25 expressing my general understanding in the</p>
<p style="text-align: right;">Page 83</p> <p>1 A Okay. It's just the way you're phrasing it,</p> <p>2 I don't necessarily want to say yes or --</p> <p>3 that's the only problem.</p> <p>4 Q All right. Fair enough.</p> <p>5 A I want to answer. I just want to make sure</p> <p>6 that there is a clean record of what I'm</p> <p>7 saying.</p> <p>8 Q All right. So macrophages formed by giant</p> <p>9 cells can persist at the site of the mesh or</p> <p>10 foreign body; is that correct?</p> <p>11 A Yes, they are there -- again, in the Anderson</p> <p>12 paper, they are there for the lifetime of the</p> <p>13 device. They're persisting.</p> <p>14 Q And when you say the Anderson paper, is that</p> <p>15 the one you identified earlier on the record,</p> <p>16 sir?</p> <p>17 A Yes, sir.</p> <p>18 Q Okay. Thank you.</p> <p>19 Now, isn't it true, Doctor, that those</p> <p>20 macrophages in foreign body cells that</p> <p>21 persist at the site of the foreign body can</p> <p>22 become quiescent?</p> <p>23 A I've seen this idea proposed. Again, I'm</p> <p>24 relying on Dr. Anderson's 2008 review. And</p> <p>25 Dr. Anderson is a member of the National</p>	<p style="text-align: right;">Page 85</p> <p>1 field without any documents in front of me.</p> <p>2 Q You're aware of the belief in the field that</p> <p>3 these inflammatory cells can become</p> <p>4 quiescent, and they do not necessarily remain</p> <p>5 activated at the site of the foreign body?</p> <p>6 A I don't -- there are ideas that -- I don't</p> <p>7 know that -- quiescent I think is a strong</p> <p>8 word. Maybe there are varying levels of</p> <p>9 activity, but I don't know that I've seen</p> <p>10 convincing proof that they are just</p> <p>11 completely quiescent. Again, if you would</p> <p>12 like me to look at a paper, I will look at</p> <p>13 one, but this is my understanding.</p> <p>14 Q What are lysosomal constituents?</p> <p>15 A Can you put some context to that? I'm not</p> <p>16 -- just to give me a phrase. Lysosomal</p> <p>17 constituents, I mean, what's the context of</p> <p>18 it?</p> <p>19 Q With regard to foreign body giant cells,</p> <p>20 whether they remain activated releasing their</p> <p>21 lysosomal constituents?</p> <p>22 A I'm just not -- I could look at something.</p> <p>23 It's hard for me to answer that just in the</p> <p>24 way that question is phrased. I would have</p> <p>25 to look at what you're referring to, because</p>

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<p style="text-align: right;">Page 86</p> <p>1 I am just not sure what you mean.</p> <p>2 Q Did you research the question of whether</p> <p>3 inflammatory cells become quiescent or</p> <p>4 deactivated at the site of a foreign body?</p> <p>5 A I don't remember specifically doing that for</p> <p>6 this particular litigation.</p> <p>7 Q Are there any books in your field considered</p> <p>8 authoritative or important to these general</p> <p>9 principles of foreign body reaction?</p> <p>10 A I don't know. There is lots of -- I mean,</p> <p>11 I've got a book on biomaterials that has --</p> <p>12 Professor David Williams has just released a</p> <p>13 book on biomaterials. There is a book</p> <p>14 Biomaterials Science by four very well-known</p> <p>15 senior scientists that discuss these ideas.</p> <p>16 You know, these are all important books.</p> <p>17 Q Let me ask you this. Is there any way to</p> <p>18 test to know whether the cells are remaining</p> <p>19 activated?</p> <p>20 A Well, that's the myeloperoxidase stain. When</p> <p>21 I see a positive stain for MPO, that's</p> <p>22 staining for that enzyme, and that's telling</p> <p>23 us that the cells are generating ROS. That's</p> <p>24 how you do it.</p> <p>25 Q Is there any other test that you can do that</p>	<p style="text-align: right;">Page 88</p> <p>1 A I understand.</p> <p>2 Q In the paper by Jim Anderson, does he state</p> <p>3 that those macrophages in foreign body cells</p> <p>4 continue to release the substances at the</p> <p>5 site of the foreign body as years continue to</p> <p>6 progress and they remain activated? Is that</p> <p>7 conclusively stated in the paper?</p> <p>8 A So I'd like to answer that by stating what</p> <p>9 Dr. Anderson does say in that paper. He says</p> <p>10 that the cells become activated, and that the</p> <p>11 foreign body reaction is present throughout</p> <p>12 the lifetime of the device. And then he</p> <p>13 qualifies that as, albeit, in some cases at a</p> <p>14 low level.</p> <p>15 So what he is saying, and then what his</p> <p>16 point is, is that as long as the device is</p> <p>17 there, this foreign reaction body is ongoing,</p> <p>18 and that these factors need to be considered</p> <p>19 in the design of the medical device. That's</p> <p>20 what he says.</p> <p>21 Q Okay. So Dr. Anderson does not state that if</p> <p>22 the cells are there, they are going to be</p> <p>23 activated and producing these substances?</p> <p>24 A I would say it's implied. It doesn't</p> <p>25 necessarily specifically state that. And I</p>
<p style="text-align: right;">Page 87</p> <p>1 would actually show those substances released</p> <p>2 by the ROS?</p> <p>3 A It's more difficult to do because they are</p> <p>4 such small molecules. The myeloperoxidase</p> <p>5 is just a very -- you know, it's a relatively</p> <p>6 straight forward stain to do.</p> <p>7 Q Do you know if the MPO stain is recognized by</p> <p>8 the American College of Pathology as a proper</p> <p>9 stain for assessing the release of that</p> <p>10 substance by ROS?</p> <p>11 A I don't know. We looked at -- you know, I</p> <p>12 published this, so it's been peer-reviewed.</p> <p>13 It was accepted as a marker of presence of</p> <p>14 oxidative conditions.</p> <p>15 Q Does Dr. Williams' paper that you referenced</p> <p>16 state with certainty that those macrophages</p> <p>17 of foreign body giant cells continue to</p> <p>18 remain activated and release substances on</p> <p>19 the surface of the biomaterial?</p> <p>20 A I think you're getting papers confused. I</p> <p>21 was referring to the Anderson 2008 paper.</p> <p>22 Q Okay. I'm sorry. So let me just ask a</p> <p>23 better question. Anytime you need to the</p> <p>24 correct me, let me know. I get these things</p> <p>25 confused.</p>	<p style="text-align: right;">Page 89</p> <p>1 would be happy to read it from the paper, but</p> <p>2 it's very strongly implied that that's what's</p> <p>3 happening in the way that it is stated.</p> <p>4 THE WITNESS: I have to go to</p> <p>5 the bathroom if you don't mind.</p> <p>6 MR. SNELL: Let's take a break.</p> <p>7 (A lunch recess is taken from</p> <p>8 12:00 to 12:50 p.m.)</p> <p>9 THE COURT: Let's take a break.</p> <p>10 BY MR. SNELL:</p> <p>11 Q Doctor, we are going to mark the Perry</p> <p>12 pathology slides that you have in your</p> <p>13 possession as Exhibit No. 2.</p> <p>14 (Deposition Exhibit No. 2 is</p> <p>15 marked for identification.)</p> <p>16 BY MR. SNELL:</p> <p>17 Q And I will hand you Exhibit 2. Just confirm</p> <p>18 for the record that those are the slides,</p> <p>19 sir.</p> <p>20 A Yes, these are the slides I was presented.</p> <p>21 Q It looks like there is three different sets,</p> <p>22 each of them wrapped in bubble wrap?</p> <p>23 A Yes.</p> <p>24 Q Am I correct, sir, that you're not relying on</p> <p>25 those pathology slides for your opinions?</p>

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<p style="text-align: right;">Page 90</p> <p>1 A That's correct.</p> <p>2 Q Do you know what type of inflammatory cells,</p> <p>3 if any, are present in Mrs. Perry's mesh?</p> <p>4 A I don't know. I didn't look at the slides</p> <p>5 under a microscope.</p> <p>6 Q You therefore would not know how many of any</p> <p>7 inflammatory cells, if they are present, were</p> <p>8 actually there, correct?</p> <p>9 A That's correct.</p> <p>10 Q When we were talking about the inflammatory</p> <p>11 cells, just so we're on the same page, I'm</p> <p>12 referring to the macrophages in foreign body</p> <p>13 giant cells?</p> <p>14 A Yes.</p> <p>15 Q Okay. So when we say chronic inflammatory</p> <p>16 cells --</p> <p>17 A Yes.</p> <p>18 Q -- are we talking about macrophages in the</p> <p>19 foreign body giant cells?</p> <p>20 A Yes.</p> <p>21 Q Okay. Do you know whether there were any</p> <p>22 chronic inflammatory cells present in</p> <p>23 Mrs. Perry's vaginal tissue before her</p> <p>24 surgeries, one of which included mesh?</p> <p>25 A I'm not aware of that information.</p>	<p style="text-align: right;">Page 92</p> <p>1 It's not going to work on a histological</p> <p>2 section. You would need mesh from the</p> <p>3 patient before it's been processed for</p> <p>4 histology to do those measurements.</p> <p>5 Q You said that was nano --</p> <p>6 A Nanoindentation could measure the brittleness</p> <p>7 of the surface degraded layer.</p> <p>8 Q Is that a particular type of test,</p> <p>9 nanoindentation?</p> <p>10 A It is.</p> <p>11 Q Is it separate and apart from some of the</p> <p>12 other testing that we've discussed?</p> <p>13 A It is. It is mechanical testing at a very</p> <p>14 small scale. I've done testing like this</p> <p>15 with a collaborator at Vanderbilt where we</p> <p>16 probed the surface with a cantilever beam,</p> <p>17 and we measure the response and the</p> <p>18 mechanical force. You can measure an elastic</p> <p>19 modulus doing this.</p> <p>20 Q You have not done any of this</p> <p>21 nanoindentation testing on Mrs. Perry's mesh,</p> <p>22 correct?</p> <p>23 A That's correct.</p> <p>24 Q Have you seen any photographs of Mrs. Perry's</p> <p>25 mesh that showed cracking?</p>
<p style="text-align: right;">Page 91</p> <p>1 Q Did you attempt to look at any of the</p> <p>2 pathology reports in Mrs. Perry's case?</p> <p>3 A No, I did not review those reports.</p> <p>4 Q Have you attempted to measure any of the</p> <p>5 reactive oxygen species in Mrs. Perry?</p> <p>6 A We talked about this earlier. I didn't do</p> <p>7 that.</p> <p>8 Q Have you attempted to do any mechanical</p> <p>9 testing of Mrs. Perry's mesh?</p> <p>10 A No.</p> <p>11 Q Are you aware of any testing done on</p> <p>12 Mrs. Perry's mesh to determine whether it</p> <p>13 became tougher after implantation?</p> <p>14 A I'm not aware of any other testing on her</p> <p>15 mesh.</p> <p>16 Q And you would not have done such testing to</p> <p>17 determine whether it became tougher, correct?</p> <p>18 A Seems like -- I'm not sure what you mean by</p> <p>19 the mesh became tougher. I mean, it seems</p> <p>20 like it would be difficult to do.</p> <p>21 Q You could test to determine whether the mesh</p> <p>22 became embrittled in Mrs. Perry, correct?</p> <p>23 A Test the outer layer, that could be done by a</p> <p>24 nanoindentation. But, again, you need an</p> <p>25 appropriate amount of mesh in the right form.</p>	<p style="text-align: right;">Page 93</p> <p>1 A I've not seen any photographs of her mesh.</p> <p>2 Q Earlier you were talking about the bonding</p> <p>3 that can occur leading to degradation of the</p> <p>4 particular atom. I don't recall if it was</p> <p>5 carbon or hydrogen.</p> <p>6 A You are referring to oxidation and a free</p> <p>7 radical attack on a tertiary carbon hydrogen</p> <p>8 bond?</p> <p>9 Q Yes, sir.</p> <p>10 A Yeah.</p> <p>11 Q So for oxidation, is that oxygen which comes</p> <p>12 and bonds with carbon or the other way</p> <p>13 around?</p> <p>14 A The details of the reaction are very complex.</p> <p>15 But, essentially, it's a radical attack, a</p> <p>16 hydroxyl radical or oxygen radical can attack</p> <p>17 that bond. The chemistry is very</p> <p>18 complicated.</p> <p>19 Q What is the difference between an oxygen</p> <p>20 molecule and an oxygen radical?</p> <p>21 A Well, it's just the nature of the chemical</p> <p>22 reaction. In the body -- and in our in vitro</p> <p>23 testing -- I can speak specifically from our</p> <p>24 in vitro testing, the solution that we</p> <p>25 created generated hydroxyl radicals, and those</p>

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<p style="text-align: right;">Page 94</p> <p>1 hydroxyl radicals attacked that carbon 2 hydrogen tertiary bond -- tertiary carbon 3 hydrogen bond. 4 The hydroxyl radicals attacked that bond, 5 and that's where the pollen becomes oxidized. 6 And then there is a number of steps in this 7 reaction, I would have to look at a paper to 8 explain it, but there is just a number of 9 steps in that chemical reaction. It's very 10 complex. 11 Q When you say the hydroxyl radicals attacked 12 the bond, is that that tertiary bond you were 13 referring to? 14 A Yes. It extracts the -- I would have to look 15 at the paper to show the exact mechanism, but 16 that tertiary carbon hydrogen bond is 17 vulnerable to an oxidative attack. But the 18 physical chemistry of that reaction is, 19 again, complex. 20 Q Is it correct that you have not seen the 21 presence of a hydroxyl radical in Mrs. Perry's 22 case? 23 A Yeah. As we have discussed before, I have 24 not done the myeloperoxidase staining or 25 looking for a radical, which would be very</p>	<p style="text-align: right;">Page 96</p> <p>1 carbon-oxygen bonds that we can detect by 2 XPS. 3 Q Have you attempted to look for the presence 4 of carbon-oxygen bond in Mrs. Perry's case? 5 A I have not done that. 6 Q Have you attempted to look for the percent of 7 carbon in Mrs. Perry's mesh? 8 A I have not done that. 9 Q Have you attempted to look for the percent of 10 oxygen in Mrs. Perry's mesh? 11 A No. 12 Q You earlier mentioned different biomaterial 13 books, one of which was your own, I believe? 14 A I edited a book, Introduction to Bond 15 Materials. It's on my CV. 16 Q What biomaterial books are used at 17 Vanderbilt? 18 A So the BME department -- I mean, chemical 19 engineering department, the biomedical 20 engineering department, teaches a course in 21 biomaterials. I'm not sure what they're 22 using now. In the past, they have used a 23 book by Johnna Temenoff on biomaterials. I 24 think they have made some changes to that 25 course. I've never taught that course, so I</p>
<p style="text-align: right;">Page 95</p> <p>1 difficult to do in her case. I have not done 2 that. 3 Q As I understand it, the presence of hydroxyl 4 groups on a surface would be indicative of 5 oxidation? 6 A It's the OH group forms in a hydroperoxide 7 intermediate. There is a hydroperoxide that 8 forms on the oxidized polypropylene, and we 9 can see that peak by IR spectroscopy. 10 Q Have you attempted to do any IR spectroscopy 11 in Mrs. Perry's case? 12 A No, I have not done that. 13 Q As I understand it, there is testing that can 14 be performed to try to assess atomic 15 percents, such as the percent carbon, percent 16 oxygen, and percent nitrogen; is that 17 correct? 18 A There is a method called x-ray photoelectron 19 spectroscopy. We will call it XPS. XPS 20 tells us what percentage of the carbon is 21 bound to other atoms. So in pure 22 polypropylene, all of the carbons should be 23 bound. Either the hydrogen or carbon, it's a 24 hydrocarbon. When polypropylene becomes 25 oxidized, we see the formation of</p>	<p style="text-align: right;">Page 97</p> <p>1 don't know all the details. 2 Q Is your book used in teaching biomaterials 3 at Vanderbilt? 4 A Not to my knowledge. But that book was 5 written for a somewhat different purpose than 6 for a teaching textbook. 7 Q I think earlier you mentioned another book 8 called Biomaterials Sciences, and it had a 9 couple of different editors or authors? 10 A So there were two well-known books. The 11 older one is -- well, I think it's called 12 Biomaterials Sciences. It was -- 13 maybe endorsed isn't the word, but the 14 Society for Biomaterials endorses this book. 15 Endorses may be a strong word. They 16 recognize this book as being an important 17 book, and there are four senior authors on 18 this book. 19 It's written more as a reference text. 20 It's difficult to teach from, because it's an 21 edited book. So it's an excellent resource 22 for study. But for teaching undergraduates, 23 it's not as accessible. So Professor David 24 Williams, who is also a lead world expert in 25 biomaterials, has written a new textbook. I</p>

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<p style="text-align: right;">Page 98</p> <p>1 contributed some figures to that textbook. 2 And Professor Williams' textbook has been 3 assessed by my colleagues in BME at 4 Vanderbilt for teaching. I'm not sure if 5 they've made a final decision whether to use 6 it. What's attractive about that book for 7 teaching is it's written by one author. So 8 it's a single-author book, and so this is 9 good for teaching undergraduates. 10 My textbook, I edited, so there are 11 chapters by individual contributors. So it's 12 just a different book. 13 Q When you were going about compiling your 14 book, did you reach out to people who you 15 felt were experts in certain fields to write 16 or contribute to particular chapters? 17 A That's how we approached editing the book, 18 that's right. That was in 2005 when I was a 19 postdoc. 20 Q What is the most recent edition of your book? 21 Is it on your CV? 22 A Well, I co-edited the first edition. There 23 is a second edition, but I didn't co-edit 24 that one. The only one that I have co-edited 25 has been published in 2006. It's on my CV.</p>	<p style="text-align: right;">Page 100</p> <p>1 Abbrevio? 2 A I have not. 3 Q Have you done any testing of any type on TVT 4 product for stress incontinence? And when I 5 stay TVT, I mean Ethicon's particular TVT 6 product. 7 A So only the testing performed at Dr. Dunn's 8 laboratory. Just to be clear, Dr. Dunn did 9 that testing. I consulted and advised. We 10 discussed it, agreed to do it, but Dr. Dunn 11 physically performed the testing. 12 Q Tell me what testing did Dr. Dunn do on an 13 Ethicon TVT device. As I had read -- and 14 I'll tell you why I'm asking. As I had read 15 your Huskey deposition testimony, he had done 16 some testing on maybe one or more AMS meshes 17 and Boston Scientific meshes. 18 A These are new testing that we've done. 19 Q Let me just back up then. So as I understand 20 it, Dr. Dunn has done some testing on Ethicon 21 TVT products? 22 A Yes. 23 Q Are you relying on that testing for your 24 opinions in the Perry case? 25 A Let me look at my opinions for a minute.</p>
<p style="text-align: right;">Page 99</p> <p>1 Q The Society for Biomaterials, you referenced 2 you're a member of that society? 3 A I am. 4 Q And the book they recognize as being an 5 important book is Biomaterials Sciences. Is 6 the title An Introduction to Materials and 7 Medicine by -- 8 A That sounds right. 9 Q -- Buddy Ratner? 10 A Buddy Ratner, Hoffman, Schoen. They're all 11 founders of the Society for Biomaterials, 12 very well-known. Jack Lemons is the other 13 author. 14 Q Did any of those authors contribute to your 15 book? 16 A I don't remember. I don't think so. 17 Q I want to ask you some questions about TVT 18 Abbrevio. I'm just trying to give you an idea 19 of where I'm going. 20 A Okay. 21 Q Because I know we went back and kind of 22 covered some things that we addressed earlier 23 with further questions. 24 A Okay. 25 Q Have you done any testing of any type on TVT</p>	<p style="text-align: right;">Page 101</p> <p>1 Yes, I am relying on that testing. So I 2 should say, I formed my opinions based on the 3 literature review. My opinions are the same 4 as they were in the Huskey case on this 5 particular topic of oxidation and 6 degradation, and this testing further 7 confirms my opinions. 8 And the testing was specifically done to 9 answer the question that Ethicon raised 10 during the trial in August, that Prolene is 11 different from polypropylene and doesn't 12 oxidize because it has antioxidants. 13 So in the testing done by Dr. Dunn, the 14 goal was to answer the question can Prolene 15 in a TVT device oxidize and degrade. And we 16 saw oxidation and degradation of the surface 17 pitting in that testing, in the oxidative 18 medium that I was describing earlier. So the 19 testing was performed to answer a very 20 specific question of -- and to answer the 21 specific question of can the Prolene 22 polypropylene oxidize. That was the purpose 23 of the test. 24 Q Where is this testing, all of the notebooks, 25 the results, the data generated from it that</p>

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<p style="text-align: right;">Page 102</p> <p>1 you are relying on?</p> <p>2 A So this is on the disk that was provided.</p> <p>3 Q Okay. Show me where on the disk that that is</p> <p>4 this TVTG testing is located.</p> <p>5 A I don't have a computer but --</p> <p>6 Q Can you use Mr. Kuntz'?</p> <p>7 MR. KUNTZ: He can.</p> <p>8 Let's go off the record for a second.</p> <p>9 (Off-the-record discussion.)</p> <p>10 BY MR. SNELL:</p> <p>11 Q Counsel is looking at the thumb drive.</p> <p>12 Obviously, I can't look at it and question</p> <p>13 the witness about 6,000 files today. Let me</p> <p>14 just get some basic information about this</p> <p>15 testing.</p> <p>16 The testing that was performed on</p> <p>17 Ethicon's TVT mesh, what specific device or</p> <p>18 devices were the subject of the testing?</p> <p>19 A I believe it was the TVT.</p> <p>20 Q The original TVT retropubic?</p> <p>21 A I believe so. And we also tested an</p> <p>22 unstabilized polypropylene controlled, it had</p> <p>23 no antioxidant.</p> <p>24 Q Okay. You said it was an unstabilized</p> <p>25 Prolene polypropylene?</p>	<p style="text-align: right;">Page 104</p> <p>1 A I am just disclosing what we did.</p> <p>2 Q This TVT retropubic device that Dr. Dunn</p> <p>3 tested, was it one single device or was it a</p> <p>4 batch or numerous ones?</p> <p>5 A I believe it was one device with three</p> <p>6 replicate pieces, three distinct pieces cut</p> <p>7 from -- it was three or four. I can't</p> <p>8 remember the details. I would have to look</p> <p>9 at it. But there were multiple replicates</p> <p>10 cut from the same mesh.</p> <p>11 Q And the unstabilized polypropylene control,</p> <p>12 where was that obtained from?</p> <p>13 A I would have to look at the document to look</p> <p>14 at the documents for the exact source, but it</p> <p>15 was purchased from a third-party vendor that</p> <p>16 sells polypropylene with antioxidants,</p> <p>17 unstabilized polypropylene.</p> <p>18 Q Do you know the vendor?</p> <p>19 A I can't remember. It's in the documents. I</p> <p>20 would have to find it.</p> <p>21 Q Do you know who purchased this control?</p> <p>22 A Dr. Dunn purchased it and did all of this</p> <p>23 work.</p> <p>24 Q You personally were not the one who did any</p> <p>25 of this testing on the TVT retropubic device,</p>
<p style="text-align: right;">Page 103</p> <p>1 A No. It's polypropylene without antioxidants.</p> <p>2 So it would be the equivalent of -- in the</p> <p>3 Liebert paper where they tested the</p> <p>4 monofilament with no stabilizers. It's a</p> <p>5 polypropylene that has no antioxidants. So</p> <p>6 it's unstabilized polypropylene I would call</p> <p>7 it.</p> <p>8 Q So you didn't test the TVT retropubic mesh</p> <p>9 with antioxidants to the TVT retropubic mesh</p> <p>10 with antioxidants?</p> <p>11 A No, we can't get TVT without the -- the TVT</p> <p>12 is made from Prolene that has that Prolene</p> <p>13 antioxidant package, because that's what we</p> <p>14 tested, that's what we could get. So we had</p> <p>15 that exemplar, Dr. Dunn had it, and we</p> <p>16 compared that to the unstabilized</p> <p>17 polypropylene. We also tested two Boston</p> <p>18 Scientific meshes, but that's not in the</p> <p>19 materials that we presented. That's</p> <p>20 different.</p> <p>21 Q You are not relying on this Boston Scientific</p> <p>22 testing for your opinions in this matter,</p> <p>23 correct?</p> <p>24 A I am not.</p> <p>25 Q Okay.</p>	<p style="text-align: right;">Page 105</p> <p>1 correct?</p> <p>2 A No. As I said previously, Dr. Dunn and I</p> <p>3 consulted, and Dr. Dunn did all of the work</p> <p>4 physically through his company.</p> <p>5 Q So am I correct that you did not do any of</p> <p>6 the physical testing of this TVT or the</p> <p>7 control?</p> <p>8 A That's right. Dr. Dunn did.</p> <p>9 Q And that was done at his company?</p> <p>10 A Yes.</p> <p>11 Q Was that testing done out of his house?</p> <p>12 A I don't know. Maybe some of it was done from</p> <p>13 his house. I don't remember.</p> <p>14 Q Do you know where the testing took place on</p> <p>15 this TVT retropubic compared to the</p> <p>16 polypropylene control?</p> <p>17 A It was done in his lab at Vanderbilt.</p> <p>18 Q Who paid for the testing that Dr. Dunn</p> <p>19 performed comparing the TVT retropubic to the</p> <p>20 unstabilized polypropylene control?</p> <p>21 A I should clarify that all of these responses</p> <p>22 I'm telling you to the best of my knowledge.</p> <p>23 And if Dr. Dunn contradicts what I'm saying,</p> <p>24 it's because I didn't remember it correctly.</p> <p>25 I believe that this testing was billed to the</p>

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<p style="text-align: right;">Page 106</p> <p>1 litigation, but Dr. Dunn would have to 2 confirm that. 3 Q Is your basis for your testimony in that 4 regard something that Dr. Dunn told you? 5 A Yes, I'm basing it on -- I have not seen 6 those invoices. That would be between 7 Dr. Dunn and plaintiff's counsel. 8 Q Did Dr. Dunn physically do all of his 9 testing? 10 A Again, I believe that he did, but I don't 11 know the details of -- he would be the one 12 that would have to speak to that. 13 Q Unfortunately, he is not identified as an 14 expert here. 15 A I understand that. 16 Q Were you present for any of the physical 17 testing of the TVT retropubic or the 18 unstabilized polypropylene control? 19 A Was I present? 20 Q Present meaning on the premises where the 21 testing was performed, such that you could 22 yourself observe the testing. 23 A Well, the testing was just very simple. 24 Dr. Dunn placed the -- I'm trying to answer 25 your question as best I can. So Dr. Dunn</p>	<p style="text-align: right;">Page 108</p> <p>1 A Same time frame. Maybe August -- it would 2 have been September of 2014 after the Huskey 3 trial. And, again, the motivation for the 4 tests was based on Ethicon's statements 5 during trial that we had not tested it and 6 couldn't -- we could not say definitively 7 that Prolene polypropylene oxidizes, and that 8 was the motivation for the test. 9 So this is what was said in Huskey trial, 10 we decided to do the test to answer that 11 specific question, can Prolene polypropylene 12 oxidize. 13 Q Now, Dr. Dunn's Vanderbilt lab, is that on 14 the premises here at Vanderbilt? 15 A Yes, his lab is at Vanderbilt. 16 Q Do you know if any graduate students or 17 other people were involved in the testing? 18 A Dr. Dunn has employees. I know that. To 19 what extent they were involved in the 20 testing, I can't speak to. Again, Dr. Dunn 21 just did all of his. I don't know those 22 details. 23 I should qualify my comment. Dr. Dunn 24 does not have employees, but I know that he 25 does pay contractors for services like he</p>
<p style="text-align: right;">Page 107</p> <p>1 placed the specimens in vials. They were 2 weighted down with glass beads in this 3 oxidative medium that I was describing that 4 simulates the environment between the 5 adherent inflammatory cells and the 6 biomaterial. I have seen those vials. 7 And then at different time points, 8 Dr. Dunn removed the test specimens, rinsed 9 and dried them, and measured RI spectra. And 10 I've seen those dried specimens. I've seen 11 the specimens, and so I have seen aspects of 12 the testing, but I didn't watch him do the 13 testing. But the testing essentially 14 involves incubating the material in a 15 solution, and then taking it out and testing 16 it by FTIR and SEM. 17 Q When was this testing on the TVT retropubic 18 device done? 19 A September and October of 2014. 20 Q And it was on a single TVT retropubic 21 exemplar, meaning that mesh had not been in 22 the body at all? 23 A That's correct. 24 Q When did you first discuss with Dr. Dunn this 25 testing on the TVT retropubic exemplar?</p>	<p style="text-align: right;">Page 109</p> <p>1 pays me. But, again, I cannot speak to how 2 he conducts his business. 3 Q Why did Dr. Dunn choose to test only one TVT 4 retropubic device? 5 A That was what we had at the time. And we 6 knew these depositions and report deadlines 7 were approaching quickly, so we moved forward 8 with what we had. 9 Q Would you have preferred to have more than 10 one TVT retropubic to test? 11 A We requested additional exemplars from 12 plaintiff's counsel. My understanding is 13 that this is a complex request and takes 14 time. We have requested additional items 15 recognizing the need to test multiple 16 meshes. But as I said, these requests can 17 take time to process, so we tested what we 18 had. 19 Q Why is there a need to test multiple meshes? 20 A I should qualify my answer I need to test. 21 By testing multiple products, it's possible 22 to show that it would happen in many of these 23 products. It's not possible to test every 24 one. But considering that the oxidation of 25 polypropylene is due to the inherent</p>

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<p style="text-align: right;">Page 110</p> <p>1 intrinsic molecular structure of 2 polypropylene, as well as the antioxidant 3 package, if those things are all the same, 4 you would expect a very similar response. 5 Like I said, it's a chemical reaction. 6 So if it's the same material with the same 7 antioxidants, you would expect to see a very 8 similar chemical reaction. We tested two 9 Boston Scientific meshes because we had to. 10 If we had had more, we could have tested more 11 and would have liked to have done that, but 12 we were limited to what we had at the time. 13 MR. SNELL: I'm going to move to 14 strike the part about Boston Scientific. 15 A I understand. I shouldn't have said that. 16 I'm sorry. 17 BY MR. SNELL: 18 Q So you would expect to see a similar response 19 you said, correct? 20 A Yes. 21 Q If you tested multiple meshes, correct? 22 A I would. 23 Q But we know from the teachings of Clave that 24 not all findings will be consistent with 25 regard to degradation, correct?</p>	<p style="text-align: right;">Page 112</p> <p>1 Journal of Biomedical Materials Research. In 2 the 1990 paper is a seminal paper where 3 Dr. Anderson discovered the effects of the 4 foreign body reaction on a biomedical device. 5 The 1993 paper he simulated. He 6 reproduced or recapitulated that same 7 oxidation and degradation in that same 8 biomaterial in vitro outside the body. So he 9 was able to show that this solution, this 10 oxidative solution that I've been talking 11 about recapitulates the oxidative conditions 12 that the biomaterial was exposed to in vitro. 13 I should qualify my previous comment when 14 I said there is no cells. There is no other 15 cell populations like fibroblasts that are 16 exerting contractile forces. There is no 17 tissue that is exerting forces. So this test 18 is isolating the effects of chemical 19 oxidation and was found to agree with in vivo 20 observations. That's the purpose of the 21 test, and those two papers have shown that. 22 So I hope I'm answering your question. 23 It reproduces certain aspects of the 24 reaction, but not every -- but the ones that 25 I just mentioned.</p>
<p style="text-align: right;">Page 111</p> <p>1 MR. KUNTZ: Objection. 2 A I think that the conditions are very 3 different. Clave is in vivo explant, so 4 there are many different factors affecting 5 oxidation. This study was purely isolating 6 the chemical reaction. The medium that we 7 used has been published by a number of 8 investigators, including me, that simulates 9 the oxidative conditions in the body. 10 So we're simulating a chemical reaction, 11 not -- there is no cells. There is no 12 tissue. It is simply examining that chemical 13 reaction, will that chemical reaction cause a 14 change in Prolene polypropylene. That was 15 the purpose of the test, so it's very 16 different from, say, Clave's study. It is 17 very specific. 18 That is why I would expect to see the 19 same changes in any mesh that we tested. 20 BY MR. SNELL: 21 Q So this study done in a lab is not under the 22 same conditions as one would see in vivo? 23 A I wouldn't -- I would qualify that -- there 24 are two papers in my reliance materials by 25 Dr. Jim Anderson from 1990 and 1993 in the</p>	<p style="text-align: right;">Page 113</p> <p>1 Q The test that was done on the TVT device does 2 not establish that an oxidative condition 3 occurs in vivo; is that correct? 4 MR. KUNTZ: Objection. 5 A Let me -- the in vitro test does not 6 establish the in vivo conditions. It's 7 recapitulating those in vivo conditions. We 8 know that this happens in the foreign body 9 reaction, and so the test is designed to 10 recapitulate that foreign body reaction in 11 the laboratory. 12 Q What are the limitations to the test as it 13 was conducted by Dr. Dunn utilizing only one 14 TVT device? 15 A Well, the limitation of the test is -- I want 16 to be very careful about my opinion. The 17 question we were asking was -- and what I was 18 presented with in trial, and I believe what 19 Dr. Shelby Thames testified for defense was 20 Prolene polypropylene doesn't oxidize. It's 21 stabilized. It's different. It's Prolene. 22 So we asked a very simple question, can 23 Prolene polypropylene oxidize. 24 We tested one mesh. And we showed that 25 in that one mesh that we tested, Prolene</p>

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<p style="text-align: right;">Page 114</p> <p>1 polypropylene oxidized. We have also showed 2 evidence of pitting and surface degradation. 3 So the limitation would be, we're not saying 4 that we saw it in every mesh, we're not 5 saying we saw it in 10,000 meshes. We're 6 saying we saw it in one mesh. And we 7 answered this question that it can oxidize. 8 Because it's a chemical reaction, I believe 9 we would see it in other meshes if we tested 10 those, but I recognize that we didn't. We 11 tested one mesh, but we did show that it can 12 happen in that one mesh. 13 Q So with that said, let's go back to my 14 question. What are the limitations of the 15 testing that Dr. Dunn did given there was 16 only one TVT mesh? 17 MR. KUNTZ: Objection, asked and 18 answered. 19 A I thought I answered it. I will try a 20 briefer answer. The limitation would be that 21 we tested one mesh. We showed that it can 22 happen. We did not estimate a probability 23 that it would happen. We tested one mesh and 24 saw that it happened in that mesh that we 25 tested.</p>	<p style="text-align: right;">Page 116</p> <p>1 events. 2 It starts to oxidize immediately when 3 it's implanted. It's colonized by 4 macrophages. I believe with a reasonable 5 degree of scientific certainty it will start 6 to oxidize upon implantation. When it 7 becomes induced, and there are much more 8 dramatic changes in physical properties is 9 unpredictable, as I've said in previous 10 testimony. Those events are unpredictable. 11 But I do believe that the test tells us 12 that the mesh can oxidize, and I would expect 13 it to oxidize under in vivo conditions due to 14 the nature of the inflammatory response that 15 we discussed. 16 MR. SNELL: Move to strike. 17 BY MR. SNELL: 18 Q One of the limitations to the test that 19 Dr. Dunn did on the single TVT retropubic 20 device was that it does not establish that 21 Prolene polypropylene degrades in vivo; is 22 that correct? 23 A It does not establish? I'm having a hard 24 time with this word establish. It supports 25 my opinions that these meshes are -- can</p>
<p style="text-align: right;">Page 115</p> <p>1 I believe the literature teaches with a 2 reasonable degree of scientific certainty 3 that it would happen in other meshes because 4 presumably they are chemically the same. I 5 didn't look at necessarily the manufacturing 6 doc, but I would presume based on my industry 7 experience that there are specifications for 8 antioxidants and Prolene. I've seen some 9 documents showings those numbers. Provided 10 those compositions are the same, I would 11 expect to see a very similar result, because 12 it is a chemical test testing the effects of 13 a specific chemical reaction. 14 BY MR. SNELL: 15 Q Is it fair to say that one of the limitations 16 with that test is that it does not establish 17 that Prolene polypropylene degrades in vivo? 18 MR. KUNTZ: Objection. 19 A I would say it doesn't establish the timing 20 in which Prolene polypropylene oxidizes in 21 vivo. The time scale at which this happens 22 would depend on many other factors, the 23 environment, the patient, I understand that, 24 but I do believe that it shows that it would 25 oxidize. It's just the timing of those</p>	<p style="text-align: right;">Page 117</p> <p>1 oxidize and degrade in vivo. 2 Q I'm not asking you whether your 3 interpretation as to whether it supports your 4 opinion. 5 MR. SNELL: So I would 6 respectfully move to strike. 7 BY MR. SNELL: 8 Q The limitation to this test that Dr. Dunn did 9 on the single TVT is that it does not 10 establish that Prolene polypropylene degrades 11 in vivo; is that correct? 12 MR. KUNTZ: Objection. He said 13 the exact same opposite. 14 A I'm struggling with the way you phrased the 15 question. I don't want to agree to that. I 16 believe with a reasonable degree of 17 scientific certainty that this test predicts 18 susceptibility to oxidative degradation. And 19 if we see it in vitro, we will see it in 20 vivo. 21 It's just the timing and the severity are 22 unpredictable, but I do believe it will 23 happen. I think that it's -- the timing and 24 the severity, the clinical consequences are 25 unpredictable. That's what I've been saying.</p>

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<p style="text-align: right;">Page 118</p> <p>1 MR. SNELL: Well, I respectfully 2 move to strike again. 3 BY MR. SNELL: 4 Q Again, I'm not asking you about 5 susceptibility to oxidation, and I'm not 6 asking you about oxidation, that particular 7 step. I'm asking you about degradation in 8 vivo. 9 So the question again. One of the 10 limitations to those tests by Dr. Dunn on the 11 single TVT is that it does not establish that 12 Prolene polypropylene degrades in vivo; is 13 that a fair statement? 14 MR. KUNTZ: Objection. 15 A You're speaking specifically of degradation? 16 BY MR. SNELL: 17 Q Yes, sir. That's why my question only said 18 degradation. 19 A Okay. I would like to explain my answer on 20 this. 21 Q Can you first agree or disagree and then 22 please feel free to explain? 23 A So you're saying that it does not establish 24 that it degrades -- 25 Q I will ask it one more time.</p>	<p style="text-align: right;">Page 120</p> <p>1 performed; is that correct? 2 A You're misunderstanding the purpose of the 3 test. 4 Q Sir, you have to listen to my questions and 5 answer them yes or no or whatever. I'm not 6 asking you about the purpose of the test and 7 all of that. 8 A That cannot be answered by a yes or no 9 question. The macrophage is not there, but 10 the consequence of the macrophage is there. 11 That's the test. 12 MR. SNELL: Move to strike. 13 BY MR. SNELL: 14 Q What macrophage -- 15 A I'm not going down on this. Go ahead. I'm 16 sorry. 17 Q Were macrophages present in the test that 18 Dr. Dunn did on the single TVT retropublic? 19 A Macrophages were not present, but what 20 macrophages produce, meaning radicals and 21 reactive oxygen was present. We generated 22 those reactive species using a chemical 23 reaction instead of a macrophage, but this is 24 an acceptable accepted approach to doing 25 that.</p>
<p style="text-align: right;">Page 119</p> <p>1 A I'm trying to give you an accurate answer, 2 and I'm struggling with how to answer this. 3 Q One of the limitations to the test that 4 Dr. Dunn performed on this single TVT 5 retropublic device was that it does not 6 establish that Prolene polypropylene degrades 7 in vivo; is that a fair statement? 8 MR. KUNTZ: Objection. 9 A I just don't know if I can agree to that. I 10 believe it -- it -- we didn't see -- I'm just 11 having a hard time with this sentence. The 12 way you phrase it, I would need to move on, 13 so I will leave this for the attorneys later. 14 But the way you are phrasing that question, 15 for now I will agree to it. But I have 16 reservations, because I don't believe it 17 captures what I'm really testifying about. 18 BY MR. SNELL: 19 Q It is a simple fact, isn't it, Doctor, that 20 this test that Dr. Dunn performed on the 21 single TVT device, it is not an in vivo test? 22 Can we agree to that? 23 A I will agree that it is not an in vivo test. 24 Q There were no macrophages put on the TVT 25 retropublic device and this test that Dr. Dunn</p>	<p style="text-align: right;">Page 121</p> <p>1 Just because a macrophage was not there 2 doesn't mean -- it's the same oxidative 3 conditions. It's just accomplished through a 4 different chemical reaction. 5 MR. SNELL: Move to strike 6 everything after macrophage was not present. 7 A I'm not going to back down. We can stay here 8 'til 5:00 arguing about this. I'm not going 9 to back down the test. 10 BY MR. SNELL: 11 Q Sir, we are going to be here multiple days. 12 I can tell you that now. 13 A Fine. But I'm not -- you're trying to put 14 words in my mouth. 15 Q No, sir. 16 MR. KUNTZ: We're not going to 17 be here multiple days. We'll get your seven 18 hours and we'll stay here as late as we can. 19 So -- 20 MR. SNELL: No. First of all, 21 you produced 6,000 pages. 22 MR. KUNTZ: It doesn't matter. 23 That's the rules under California. We have 24 no obligation to produce at the start of his 25 depo materials he relied on. There is no</p>

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<p>1 obligation under California state law to do 2 that. We have complied. We have brought a 3 disk and brought the materials responsive to 4 the deposition. That is the only thing that 5 is required under California law. I want to 6 make this clear. We have no duty to produce 7 before the depo anything, zero. 8 MR. SNELL: That's fine, if 9 that's your position. 10 MR. KUNTZ: Okay. 11 BY MR. SNELL: 12 Q Am I correct, sir, that there were no foreign 13 body giant cells that were used in Dr. Dunn's 14 test? 15 A My answer is the same. The cells weren't 16 there, but the reaction products were. 17 MR. SNELL: Move to strike after 18 the cells were not there. 19 A These are unreasonable questions. And this 20 deposition is going to get more hostile if 21 you keep going down this line of questioning, 22 just to put it out there. 23 Q Sir, as the witness, I'm allowed to ask you 24 questions. You may not like the question, 25 but you have to answer the questions.</p>	<p>1 is it that you believe this test on this 2 single TVT device compared to the control 3 shows? 4 A I believe that it shows Prolene polypropylene 5 used to manufacture the TVT device can 6 oxidize and degrade under oxidative 7 conditions similar to those experienced in 8 the human body after implantation. 9 Q What documents or files out of those 6,000 10 plus show the oxidation? 11 A The oxidation is evidenced by FTIRs spectra 12 that were measured in weeks zero, one, two, 13 three, four and five. In the FTIRs spectra, 14 we saw minimal hydroxyl and carbonyl peaks 15 until week five, where we saw a significant 16 increase in the magnitude of the hydroxyl 17 and/or carbonyl peaks, which was indicative 18 of a chemical induction. 19 Q So what are the file names and the documents 20 that showed this out of the 6,000? 21 A I don't remember the file names. 22 Q Well, I'm entitled to know them. 23 A I know. And I have to look at it. I don't 24 have it here with me. I know that you're 25 entitled to have it, but I don't have it here</p>
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<p>1 A But the questions are being phrased that 2 you're trying to misrepresent my testimony 3 and misrepresent what I'm saying. 4 Q I'm not trying to misrepresent your 5 testimony. 6 A You are. 7 Q I'm asking you a factual question. 8 A And the question is -- 9 Q Was there a horse in the room at the time of 10 the test, yes or no? No. 11 Was there a macrophage in the test, yes 12 or no? 13 The interpretation, I will get to that, 14 but I have simple questions, sir, and I'm 15 entitled to simple answers if they're simple 16 questions. You can talk to Mr. Kuntz all 17 night long about your interpretation. That's 18 fine. But I'm actually going to ask you 19 about your interpretation too. 20 A And I'm entitled to answer questions as I 21 need to. And I'm not going to be put into 22 this difficult position of having things 23 recorded as my testimony that's not what I've 24 ever been saying. 25 Q You would agree that -- let me back up. What</p>	<p>1 in front of me. 2 MR. KUNTZ: He does have it. 3 MR. SNELL: Out of the 6,000, 4 you think I am some kind of scientist and can 5 pick out this FTIR testing? 6 MR. KUNTZ: The rules are the 7 rules, Burt. You gave us testing two weeks 8 before trial. I don't cry about it. We 9 follow the rules. 10 MR. SNELL: All I'm asking him 11 is to identify it. 12 MR. KUNTZ: That's fine. We'll 13 sit here and he can identify it. Let's pull 14 it up. 15 MR. SNELL: That's what I 16 thought we were doing. 17 MR. KUNTZ: If that's how you 18 want to spend your seven hours with him, 19 let's do it. 20 MR. BOWMAN: There is a folder 21 named FTIR on the drive that was given to 22 you. It's already been disassembled and 23 separated out. There's FTIR, and there's 24 SEM, and XPS. 25 MR. KUNTZ: I'm trying to get</p>

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<p style="text-align: right;">Page 126</p> <p>1 you a link, so you can pull them up.</p> <p>2 BY MR. SNELL:</p> <p>3 Q What documents, if any, in this study that</p> <p>4 Dr. Dunn did on the single TVT device show</p> <p>5 that the Prolene polypropylene degrades?</p> <p>6 A There are SEM images at weeks zero and five,</p> <p>7 I believe. What the name of that file is, I</p> <p>8 don't know. I will have to look at the</p> <p>9 folders to try to find it.</p> <p>10 Q Okay. And what is it about those SEM images</p> <p>11 that you believe shows degradation?</p> <p>12 A There are changes in the surface, including</p> <p>13 pitting, flaking, changes to the surface that</p> <p>14 can be observed by SEM.</p> <p>15 Q How deep is the pitting?</p> <p>16 A I don't know. I would have to look at the</p> <p>17 image again to see it.</p> <p>18 Q How much material is flaking off?</p> <p>19 A Again, I would have to look at it to see</p> <p>20 that. We saw SEM is -- we were just really</p> <p>21 looking to see if it's there or not. It's</p> <p>22 difficult to be more quantitative as we can</p> <p>23 be with the FTIR, but we saw evidence of</p> <p>24 changes to the surface.</p> <p>25 Q Did you attempt to quantify the pitting?</p>	<p style="text-align: right;">Page 128</p> <p>1 the time point at which we did XPS. It's in</p> <p>2 the data. I just can't remember it.</p> <p>3 Q What, if anything, did the XPS show?</p> <p>4 A The XPS revealed the evidence of</p> <p>5 carbon-oxygen bonds on the surface of the</p> <p>6 TVT.</p> <p>7 Q How many carbon-oxygen bonds were seen?</p> <p>8 A So XPS, we did three distinct measurements at</p> <p>9 three surfaces on the fiber. We cannot see</p> <p>10 microscopically where we're testing, so it's</p> <p>11 not possible to tell whether we're testing</p> <p>12 where there is an area of active degradation</p> <p>13 or not. Does that make sense?</p> <p>14 There is areas of pitting on the fibers,</p> <p>15 and then there is areas on the fibers that we</p> <p>16 don't see the pitting. When we do the XPS</p> <p>17 measurements, we're not exactly sure of where</p> <p>18 on the fiber we're probing. We actually</p> <p>19 picked three spots. And the XPS measurement</p> <p>20 tells us at that particular spot that is</p> <p>21 being probed, what the percentage of the</p> <p>22 carbon is bound to oxygen. And we saw many</p> <p>23 spots. It's in the data. I just can't</p> <p>24 remember the exact numbers, but we saw many</p> <p>25 spots on the surface where we saw the</p>
<p style="text-align: right;">Page 127</p> <p>1 A We were working on it. In the amount of time</p> <p>2 we had to pull this together, we haven't had</p> <p>3 time to do it yet.</p> <p>4 Q You attempted to quantify the amount of</p> <p>5 flaking?</p> <p>6 A Same answer.</p> <p>7 Q Not yet?</p> <p>8 A Not yet.</p> <p>9 Q Is there anything else about this test that</p> <p>10 Dr. Dunn did on the single TVT device?</p> <p>11 A Anything else that -- I'm sorry. Go ahead.</p> <p>12 Q That's okay.</p> <p>13 A It shows degradation.</p> <p>14 Q It shows degradation besides the SEM images?</p> <p>15 A No, degradation was assessed by SEM.</p> <p>16 Q Oxidation was assessed by FTIR?</p> <p>17 A That's correct. And there was XPS testing</p> <p>18 for some of those samples as well.</p> <p>19 Q You said there was XPS testing for some of</p> <p>20 the samples. What do you mean?</p> <p>21 A Well, I didn't say that very accurately. I</p> <p>22 can't remember all of the time points at</p> <p>23 which we ask did XPS. I know we did FTIR at</p> <p>24 zero, one, two, three, four and five. We did</p> <p>25 SEM at zero and five, but I can't remember</p>	<p style="text-align: right;">Page 129</p> <p>1 existence of carbon-oxygen bonds.</p> <p>2 Q Should there be no carbon-oxygen bonds?</p> <p>3 A There should be no carbon-oxygen bonds in</p> <p>4 nonoxidized polypropylene, polypropylene that</p> <p>5 has not been oxidized. I don't want to use</p> <p>6 pure, because there is other additives. But</p> <p>7 polypropylene that has not been oxidized</p> <p>8 should not reveal evidence of carbon-oxygen</p> <p>9 bonds.</p> <p>10 It's similar to FTIR, except FTIR is</p> <p>11 telling us the functional groups, and XPS is</p> <p>12 telling us the types of bonds.</p> <p>13 Q Were there any inconsistent findings in this</p> <p>14 test done by Dr. Dunn?</p> <p>15 A Not that I'm aware of.</p> <p>16 Q Did you put this -- the unstabilized</p> <p>17 polypropylene control, what was that control?</p> <p>18 A It was a polypropylene pellet that was</p> <p>19 purchased from a third-party vendor. I don't</p> <p>20 remember the name of the vendor, but I</p> <p>21 believe it is in Dr. Dunn's testing documents</p> <p>22 where the polypropylene has no antioxidant</p> <p>23 added to it.</p> <p>24 Q Are the documents in there that reflect what</p> <p>25 type of polypropylene pellet and where that</p>

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<p>1 pellet was from? Is that in the files?</p> <p>2 A I believe that it is. If it's not, we can</p> <p>3 get that. That's a known. Dr. Dunn has that</p> <p>4 information. And I should note that Dr. Dunn</p> <p>5 has all of the samples from this testing as</p> <p>6 well. We still have the material. We saved</p> <p>7 everything.</p> <p>8 Q Is it kept at his lab or his house?</p> <p>9 A I'm not sure where he is storing that, but he</p> <p>10 has stored that in dark containers protected</p> <p>11 from the light. He can speak to that. He's</p> <p>12 storing the material. I'm not sure where.</p> <p>13 Q So this polypropylene pellet that was used as</p> <p>14 an unstabilized control, am I correct that it</p> <p>15 had not been extruded or gone through any</p> <p>16 manufacturing process whatsoever?</p> <p>17 A I believe that it had probably at least been</p> <p>18 extruded because we bought it as pellets. So</p> <p>19 my understanding is they melt the</p> <p>20 polypropylene -- I don't know the answer to</p> <p>21 that. Dr. Dunn would be able to talk about</p> <p>22 the history of the sample.</p> <p>23 Q Do you know if this polypropylene pellet that</p> <p>24 you tested was a pellet used in any stress</p> <p>25 incontinence sling devices?</p>	<p>1 each time point because we have three or four</p> <p>2 replicates.</p> <p>3 I can't remember the exact number, but we</p> <p>4 have enough replicates that we can speak to</p> <p>5 the significant differences between groups</p> <p>6 as a function of time.</p> <p>7 Q But that analysis has not been done yet,</p> <p>8 correct?</p> <p>9 A It has not been done because we are still</p> <p>10 quantifying the results.</p> <p>11 Q Who will do the testing for clinical</p> <p>12 significance?</p> <p>13 A I don't know yet. We're still discussing</p> <p>14 this.</p> <p>15 Q Who are you considering to do statistical</p> <p>16 significance testing in this test --</p> <p>17 A Dr. Dunn or I. One of us will do it.</p> <p>18 Q Are you a statistician?</p> <p>19 A I'm not a statistician, but I've done similar</p> <p>20 statistical testing in any papers that I've</p> <p>21 published where we compared differences</p> <p>22 between material groups and time using a one-</p> <p>23 or two-way ANOVA. That's a common method.</p> <p>24 Q But you're going to be testing over different</p> <p>25 time points, correct?</p>
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<p>1 A I have no way of knowing that without knowing</p> <p>2 the supplier of the pellet.</p> <p>3 Q How was it that Dr. Dunn came to decide on</p> <p>4 which particular polypropylene pellet from a</p> <p>5 certain manufacturer he was going to obtain?</p> <p>6 A So in his previous testimony, Dr. Dunn has</p> <p>7 investigated a number of polypropylene cases,</p> <p>8 and he's done similar testing before in which</p> <p>9 he used unstabilized polypropylene controls,</p> <p>10 so that decision would have been based on his</p> <p>11 experience with prior testing.</p> <p>12 Q The unstabilized polypropylene control, what</p> <p>13 tests were done that on that?</p> <p>14 A The same tests as were done on TVT. So it</p> <p>15 would have been XPS, FTIR and SEM.</p> <p>16 Q Did you attempt to calculate any clinical</p> <p>17 significance of any findings in this test</p> <p>18 that Dr. Dunn did?</p> <p>19 A We are still doing the quantitative analysis,</p> <p>20 but we will calculate -- how shall I say this</p> <p>21 -- statistical significance between groups as</p> <p>22 a function of time. So we would compare the</p> <p>23 TVT group to the unstabilized polypropylene</p> <p>24 group. We would compare at each time point.</p> <p>25 And we would compare within each group at</p>	<p>1 A You mean statistically?</p> <p>2 Q Yeah.</p> <p>3 So you will be testing over multiple time</p> <p>4 points, correct?</p> <p>5 A Yes.</p> <p>6 Q So, therefore, you will need to apply a</p> <p>7 Bonferroni or some type of multiple testing</p> <p>8 equation, correct?</p> <p>9 A Yes. We typically do this. I believe it</p> <p>10 will be a two-way ANOVA with a Bonferroni</p> <p>11 correction. But, again, we haven't decided</p> <p>12 that yet.</p> <p>13 Q So as you sit here today, you cannot state</p> <p>14 that the test results were statistically</p> <p>15 significant upon applying the proper</p> <p>16 statistical testing?</p> <p>17 A We haven't done it yet. The differences</p> <p>18 appear to be large, but we have to do the</p> <p>19 statistics for the FTIR testing. I don't</p> <p>20 know what we will be able to do yet on the</p> <p>21 SEM. We are discussing that.</p> <p>22 Q So the FTIR testing is the testing that you</p> <p>23 intend to do statistical significance testing</p> <p>24 upon?</p> <p>25 A Yes.</p>

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<p style="text-align: right;">Page 134</p> <p>1 Q And the SEM images, because you only took</p> <p>2 them at limited time points, zero and five</p> <p>3 weeks, you do not know whether there is</p> <p>4 enough data to generate statistical</p> <p>5 significant findings?</p> <p>6 MR. KUNTZ: Objection.</p> <p>7 A I wouldn't say it that way. I would say in</p> <p>8 SEM, we are looking at specific locations.</p> <p>9 We can't sample the entire mesh area. So</p> <p>10 it's -- we're evaluating. We haven't decided</p> <p>11 yet what to do with it.</p> <p>12 BY MR. SNELL:</p> <p>13 Q Is it fair to say as you sit here today, you</p> <p>14 have not decided whether or not to do</p> <p>15 statistically significant calculations upon</p> <p>16 the SEM testing part of the test?</p> <p>17 A That's right.</p> <p>18 Q For the XPS portion of this test, have you</p> <p>19 attempted to do any statistical significance</p> <p>20 calculations?</p> <p>21 A Not yet. XPS is similar to SEM, in that</p> <p>22 we're limited to a relatively small area on</p> <p>23 the surface of the mesh, so we have a similar</p> <p>24 sampling concern. So we haven't yet decided</p> <p>25 -- with XPS we were more interested in</p>	<p style="text-align: right;">Page 136</p> <p>1 Q Well, you had a whole sling, correct?</p> <p>2 A Yes.</p> <p>3 Q That's enough to do molecular weight testing</p> <p>4 on, correct?</p> <p>5 A It's difficult for us because we have to send</p> <p>6 these samples off to an external laboratory</p> <p>7 that requires a rather large sample size.</p> <p>8 And we would also want to analyze the</p> <p>9 molecular weight of that outside degrade and</p> <p>10 surface layer would be the most informative.</p> <p>11 So then the material requirements for doing</p> <p>12 that testing are pretty limiting, so we</p> <p>13 didn't do it.</p> <p>14 We believed that the FTIR and the SEM</p> <p>15 would provide similar information about the</p> <p>16 breakdown in the structure at the surface.</p> <p>17 And FTIR and SEM are commonly used by many</p> <p>18 investigators in these types of studies. So</p> <p>19 that's why we did the study the way that we</p> <p>20 did.</p> <p>21 Q Is it correct or not that you had enough</p> <p>22 material, considering you had a whole sling,</p> <p>23 to look at the molecular weight?</p> <p>24 MR. KUNTZ: Objection.</p> <p>25 A I don't know that we did, because we would</p>
<p style="text-align: right;">Page 135</p> <p>1 confirming the existence of those</p> <p>2 carbon-oxygen bonds.</p> <p>3 XPS is a useful technique for showing</p> <p>4 that the carbon is, in fact, chemically bound</p> <p>5 to the oxygen. And so we use XPS as a method</p> <p>6 to support the FTIR findings.</p> <p>7 Q But to date, no statistical significance</p> <p>8 testing has been done on the XPS portion; is</p> <p>9 that right?</p> <p>10 A It has not been done.</p> <p>11 Q Did you attempt to analyze molecular weight</p> <p>12 in this test?</p> <p>13 A We did not.</p> <p>14 Q Why not?</p> <p>15 A Molecular weight measurements require a</p> <p>16 considerable amount of material. Molecular</p> <p>17 weight measurements also aren't as -- with</p> <p>18 molecular weight, we are sampling the entire</p> <p>19 fiber. Whereas with these other methods,</p> <p>20 it's more the surface of the fiber. So it</p> <p>21 takes a lot of material, and it's difficult</p> <p>22 to isolate the effects of what's happening on</p> <p>23 the surface. In other words, it would take a</p> <p>24 lot of material to do that, and we didn't</p> <p>25 have that much.</p>	<p style="text-align: right;">Page 137</p> <p>1 have required separate replicates for that.</p> <p>2 And Dr. Dunn can speak to this better than I</p> <p>3 can, but there is not a lot of polymer in</p> <p>4 that -- I mean, it's a mesh. And so we</p> <p>5 needed to have separate replicates for the</p> <p>6 GPC. And we would have to have rather large</p> <p>7 samples in order to send them off for</p> <p>8 molecular weight analysis because we can't do</p> <p>9 it at Vanderbilt. We don't have the</p> <p>10 equipment.</p> <p>11 So it would have taken considerably more</p> <p>12 material, and I don't know that we had it.</p> <p>13 But, again, Dr. Dunn can speak to that.</p> <p>14 BY MR. SNELL:</p> <p>15 Q Do you know if Dr. Dunn has done molecular</p> <p>16 weight GPC testing on other mesh</p> <p>17 manufacturers' slings?</p> <p>18 A He has done some testing on exemplars in the</p> <p>19 past. But, again, my recollection of this is</p> <p>20 we had to send away a fairly significant</p> <p>21 amount of material. This is what I remember.</p> <p>22 Again, Dr. Dunn would be able to address that</p> <p>23 better.</p> <p>24 Q Did you discuss doing GPC molecular weight</p> <p>25 testing and decided not to do it or is this a</p>

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<p style="text-align: right;">Page 138</p> <p>1 test that just did not really enter into your 2 mind? 3 A Oh, we discussed it. We certainly discussed 4 it. Our conclusion was with the amount of 5 material that we had and the amount of time 6 that we had, it made the most sense to focus 7 on FTIR and SEM for this round of testing 8 and XPS. We could do those tests with a 9 single set of replicates and save those 10 samples. 11 Keep in mind too, I don't think I was 12 very clear on this point. But when I say 13 zero, one, two, three, four, five, that's 14 separate materials for each time point 15 multiplied by three or four replicates for 16 each time point, so you can see this is 17 getting to be a rather large number of mesh 18 particles. 19 Considering the time constraints we had, 20 and the amount of material we had, we 21 considered many different types of testing, 22 XPS, DSC, all of this different testing that 23 has been reported in the literature. We 24 decided to focus on those three to answer the 25 specific question of can it oxidize. FTIR</p>	<p style="text-align: right;">Page 140</p> <p>1 different reaction mechanism. But the end 2 product is the same, these hydroxyl radicals. 3 Q I think you said that you are doing this in 4 vitro. That's not correct, is it? 5 A Doing what in vitro? 6 Q Let me back up. I heard you say something 7 that just threw me off there. 8 A Okay. 9 Q When you put the TVT in this other control -- 10 can I call it a solution? 11 A Yes. 12 Q Is there a specific common name that I can 13 use? 14 A We can call it oxidative solution if you 15 like. 16 Q I don't like that. 17 A You don't like that. Of course, you don't 18 like that, do you? 19 Q Try again. 20 MR. BOWMAN: I've got a 21 suggestion. 22 MR. SNELL: What? 23 MR. BOWMAN: The Anderson 24 solution. 25 THE WITNESS: We can call it the</p>
<p style="text-align: right;">Page 139</p> <p>1 and XPS, we believe were probably the best 2 choices for answering that question of can it 3 oxidize because they're chemical analyses. 4 That was the rationale for why we did it. 5 Q This medium that you put the samples into 6 which you believe mimics what a macrophage 7 can produce in the body, what specific 8 compounds or chemicals of the macrophage does 9 this compound consist of? 10 A I think I know what you mean. So the 11 chemical reaction, cobalt chloride reacts 12 with hydrogen peroxide. Again, hydrogen 13 peroxide is a substrate for this enzyme, 14 myeloperoxidase or MPO in the inflammatory 15 cells. That chemical reaction produces 16 hydroxyl radicals, OH radical. And those 17 hydroxyl radicals are the species that attack 18 the polypropylene as we've discussed 19 previously. 20 So it generates those hydroxyl radicals, 21 which are a form of reactive oxygen species 22 in the body. Instead of generating this 23 reactive oxygen species through a 24 myeloperoxidase catalyzed reaction in a cell, 25 we are doing this reaction in vitro by</p>	<p style="text-align: right;">Page 141</p> <p>1 solution, that's fine. 2 BY MR. SNELL: 3 Q Let's get really simple, though. Just so I 4 understand, that solution, what is it made 5 of? 6 A Okay. I can explain -- and, again, this is 7 in the documents, but we mix a solution of 8 cobalt chloride. 9 Q Okay. So that's a molecule of cobalt bound 10 with chloride? 11 A I believe it's COCL₂. Is it CL₂ or CL₃? I 12 can't -- it's cobalt chloride. It's either 13 COCL₂ or CL₃. I just don't have it 14 memorized. But cobalt chloride reacts with 15 hydrogen peroxide, H₂O₂. So the solution is 16 20 percent H₂O₂, hydrogen peroxide. I don't 17 remember the concentration of cobalt 18 chloride, but it's again in the SOP. 19 We mix those together, and they react to 20 give reaction products, including hydroxyl 21 anion, that's OH minus. That's a basic 22 solution. Plus OH radical, that's OH dot, so 23 hydroxyl radical. And then there is a valence 24 change on the cobalt. I can't remember the 25 changes it's valenced.</p>

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<p style="text-align: right;">Page 142</p> <p>1 But the main reaction product is that 2 hydroxyl radical that's simulating the 3 reactive oxygen species formed by these 4 inflammatory cells in vivo. 5 Q Okay. So the hydroxyl radical simulates the 6 reactive oxygen species from the macrophages 7 in foreign body giant cells? 8 A It is. So the foreign body giant cells and 9 macrophages produce a number of reactive 10 oxygen species, and hydroxyl radicals are one 11 of them. So in the in vitro test, we are 12 producing those hydroxyl radicals and the 13 Bonferroni ROS species produced by the 14 inflammatory cells in vivo or in vitro. They 15 do this in vitro as well. 16 Q How do you know that macrophages in foreign 17 giant body cells produce hydroxyl radicals in 18 any particular case? 19 A It's been published in the Dr. Anderson 20 papers that I mentioned that when these 21 inflammatory cells adhere to the biomaterial 22 surface, they secrete a number of these 23 reactive oxygen species, including the 24 hydroxyl radicals. 25 Q How much hydroxyl radical do they produce?</p>	<p style="text-align: right;">Page 144</p> <p>1 implanted subcutaneously. That was -- the 2 purpose of that control was to give us some 3 idea of the relative time scale to relate our 4 tests to in vivo conditions as an 5 approximation. 6 Q In vivo in a hamster, though, not a person? 7 A Yes, in vivo in a hamster in a subcutaneous 8 space, not the pelvic -- it could be much 9 faster in a pelvic floor. But it was a 10 suture implanted subcutaneously is what 11 Liebert did. 12 Q What is the rate of induction of Prolene 13 polypropylene in the pelvic floor? 14 A We cannot determine that from this test. 15 There are many factors that affect that. 16 Q Is it correct that you do not know how much 17 of the hydroxyl radical is produced in the 18 solution used by Dr. Dunn? 19 A I'm not sure if that's known how -- no, I 20 don't know that we know that, but -- 21 Q Well, let's see if we can do this. It would 22 seem to me to be common sense that the amount 23 of hydroxyl radicals that would be produced in 24 vivo would be somewhat dependent upon the 25 number of macrophages; is that correct?</p>
<p style="text-align: right;">Page 143</p> <p>1 A I don't know that anybody has measured that. 2 Q How much hydroxyl radical is produced in this 3 test that mesh was put into? 4 A We don't know. But the reason we ran the 5 polypropylene control, I can try to answer 6 that. So we know from Liebert, Liebert took 7 the monofilament, the unstabilized 8 polypropylene, and planted it subcutaneously 9 in a hamster, and he saw a chemical 10 induction. He saw oxidation induction of 11 this oxidation reaction at 108 days. Okay. 12 So in our study -- that is 108 days to 13 induction. That is in vivo in that hamster 14 model, in vivo in the hamster model. In our 15 study, we saw induction between days 21 and 16 28 for unstabilized polypropylene control. 17 So if you average that, just to give you an 18 approximation to try to answer your question, 19 somewhere between 21 and 28 -- let's call 20 that 25 days, and Liebert saw induction in 21 vivo at around 100 days. 22 That tells us that events are happening 23 in our in vitro test about four times faster 24 than they happen in that in vivo hamster 25 model, which is a subcutaneous suture</p>	<p style="text-align: right;">Page 145</p> <p>1 A That would be one factor. The extent of the 2 inflammatory reaction would be one factor 3 that would affect induction time. 4 Q So if there were 1,000 macrophages present, 5 the ability of hydroxyl radicals to be 6 produced quantity-wise would be much greater 7 than if only ten macrophages were present. 8 Is that a fair scientific statement? 9 A You're saying that you would expect more ROS 10 with more macrophages? Is that what you're 11 saying? 12 Q No. 13 A Okay. Say it again. I didn't get it. 14 Q The potential amount of hydroxyl radicals that 15 could be produced would be higher if there 16 were 1,000 macrophages present as opposed to 17 only ten. Is that a fair scientific 18 statement? 19 A Present on like the -- 20 Q Present at the mesh, present at the tissues. 21 A Per area of something like this, right? 22 Q Per the same area? 23 A Yeah. I mean, I think this is equivalent to 24 what I said. If you have more macrophages 25 per area, more foreign body giant cells, that</p>

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<p style="text-align: right;">Page 146</p> <p>1 is a factor. I mean, certainly that's a 2 factor. 3 But, again, I want to emphasize that the 4 point of the tests was not to calculate the 5 rate of -- at which through the time at which 6 induction happens. It was just to answer 7 this question, can it oxidize, can it become 8 induced, can it degrade. That was the 9 purpose of the tests. 10 So we were not trying to say use these 11 data to calculate the induction time of 12 Prolene mesh in the vaginal space. There 13 were a number of factors affecting this. All 14 this test shows is that it happens. It can 15 oxidize and degrade. That was the purpose. 16 Q What is the size of the solution that you put 17 the single TVT device in? 18 A These were vials. I don't know. Maybe 20 19 milliliter vials. I can't remember the size 20 of them. They were maybe that tall and maybe 21 that big around (indicating). They were 22 vials. 23 Q So you put a piece of the mesh in the vial, 24 and the vial had the solution? 25 A Yes.</p>	<p style="text-align: right;">Page 148</p> <p>1 things as well. 2 I would rather say that there is lots of 3 factors that can affect this. And it's 4 basically accelerated by -- it happens about 5 four times faster than what Liebert observed 6 in that hamster model. I can say that. But 7 how many macrophages, I -- we don't know how 8 many macrophages Liebert observed. So it's 9 very difficult to calibrate it to that level 10 of detail. 11 Does that make -- 12 Q I guess maybe if I can back up and just make 13 this question as simple as possible. 14 A Okay. Yeah. 15 Q Are there any documents that are in those 16 test files that say for this solution, for a 17 given amount of the solution, that is the 18 equivalent to the hydroxyl radicals that can 19 be produced by Y number of macrophages? 20 A I don't know that that correlation exists. I 21 don't know. 22 MR. SNELL: Okay. Let's take a 23 break. 24 (A brief recess is taken from 25 3:25 to 3:45 p.m.)</p>
<p style="text-align: right;">Page 147</p> <p>1 Q Were all of the vials filled with the same 2 amount of solution? 3 A Yes. I believe those -- I can't remember the 4 number, but Dr. Dunn controlled for that. 5 Q As you sit here, do you know how much 6 solution was put in each bottle? 7 A I don't remember the number. It was in the 8 range of tens of milliliters. It wasn't more 9 than 100. I don't remember the number. 10 Dr. Dunn would know. 11 MR. KUNTZ: Can we take a break? 12 We've been going for one hour and 45 minutes, 13 almost two hours. 14 MR. SNELL: Yeah. 15 BY MR. SNELL: 16 Q One other question while we are taking about 17 these vials and solutions. How many 18 macrophages does one vial equate to? 19 A I don't know the answer to that. The best 20 way I can answer this -- and I want to be 21 responsive. But the best way I can answer 22 this is compared to Liebert, we are seeing an 23 acceleration of about a factor of four. 24 Could that mean that there is four times as 25 many -- it could, but it could mean other</p>	<p style="text-align: right;">Page 149</p> <p>1 (Deposition Exhibit No. 3 is 2 marked for identification.) 3 BY MR. SNELL: 4 Q Dr. Guelcher, we are back on the record. We 5 have marked as Exhibit 3, the thumb drive, 6 that has the different documents, reliance 7 materials, etc., that you brought to the 8 deposition, correct? 9 A That's correct. 10 Q And what we're doing now, we are looking 11 under -- there is a folder called Guelcher 12 Reliance Docs that we're going to look under. 13 And we are going to look for test materials, 14 correct? 15 A That's correct. 16 Q And then under that there is a subfolder 17 called In Vitro Testing. Is that a folder 18 that you're looking at? 19 A Yes, I believe there is a folder called in 20 vitro testing. 21 Q And the in vitro testing folder has test 22 information pertaining to this test that you 23 testified about earlier where Dr. Dunn 24 conducted the test on the single TVT 25 retropubic device compared to the</p>

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<p style="text-align: right;">Page 150</p> <p>1 polypropylene pellet?</p> <p>2 A That's correct.</p> <p>3 Q Now, within that in vitro testing folder,</p> <p>4 there are additional subfolders, correct?</p> <p>5 A That's correct.</p> <p>6 Q All right. So where is the study protocol?</p> <p>7 A Okay. I'm going to have to look for that.</p> <p>8 MR. KUNTZ: Again, there is a</p> <p>9 folder called protocols.</p> <p>10 MR. SNELL: I hear you. I just</p> <p>11 want the witness to tell me that it's</p> <p>12 actually in there and show me where it is.</p> <p>13 A I'm looking. Okay. Study design and</p> <p>14 protocols. There is a folder called study</p> <p>15 design and protocols.</p> <p>16 BY MR. SNELL:</p> <p>17 Q Okay. Give me a second. I'm in the study</p> <p>18 design and protocols folder. And where is</p> <p>19 the study protocol?</p> <p>20 A Okay. There is -- I believe it's the</p> <p>21 oxidative media Preparation file. Let me</p> <p>22 look at that and I believe that is it. So</p> <p>23 that is what I was calling the SOP. It says,</p> <p>24 Guelcher labs standard operating procedure</p> <p>25 oxidative media preparation. This is how we</p>	<p style="text-align: right;">Page 152</p> <p>1 for that.</p> <p>2 Okay. So I found it. I believe the file</p> <p>3 is called in vitro mesh testing sample ID's.</p> <p>4 There is an Excel file in that same folder</p> <p>5 that we were talking about.</p> <p>6 Q Okay.</p> <p>7 A And you can see that all of the sample</p> <p>8 numbers are listed here. And if you scroll</p> <p>9 to the bottom of that spreadsheet, you will</p> <p>10 see procedure. And so if you look on the</p> <p>11 procedure, line number five, place 5</p> <p>12 milliliters of oxidative media in each file.</p> <p>13 So that would be -- and then he has notes on</p> <p>14 what he did. So it's 5 mills, approximately 5</p> <p>15 milliliters of the media, of solution, in</p> <p>16 each file.</p> <p>17 Q In Anderson's paper, did he use 5 milliliters</p> <p>18 of solution?</p> <p>19 A I don't remember the number that he used or</p> <p>20 that I used in my papers. I don't remember</p> <p>21 that number.</p> <p>22 Q Do you know if you deviated from the amount</p> <p>23 that Anderson used in this test?</p> <p>24 A I don't know. I'd have to check it.</p> <p>25 Q Did Dr. Dunn decide the procedure to use</p>
<p style="text-align: right;">Page 151</p> <p>1 prepared the medium that you were asking me</p> <p>2 about.</p> <p>3 So it has the recipe for -- it's CoCL₂,</p> <p>4 cobalt chloride hexahydrate, 30-percent</p> <p>5 hydrogen peroxide solution and water. And</p> <p>6 these materials are mixed to make the 1 liter</p> <p>7 master batch, and the procedures are all</p> <p>8 listed here for that. That is how we get the</p> <p>9 solution.</p> <p>10 Q And how much is put into each of the vials?</p> <p>11 A I will have to look at a different procedure,</p> <p>12 because I think this is just the master</p> <p>13 batch. Let me find it.</p> <p>14 Q Before you leave that document, at the bottom</p> <p>15 left it says, ADT dash last edit 9/15/14?</p> <p>16 A Yes.</p> <p>17 Q Who is ADT?</p> <p>18 A That's my graduate student, Anne Talley. She</p> <p>19 is the one who has been maintaining this</p> <p>20 draft that I have approved.</p> <p>21 You asked about what, how much is added,</p> <p>22 the volume?</p> <p>23 Q Yes, the volume added to the vial of the</p> <p>24 solution.</p> <p>25 A Okay. I am going to have to go back and look</p>	<p style="text-align: right;">Page 153</p> <p>1 approximately 5 milliliters of oxidated</p> <p>2 media in each file?</p> <p>3 A I don't know that the Anderson paper</p> <p>4 specified this level of detail. We did</p> <p>5 discuss this. The Anderson paper did not</p> <p>6 present a procedure in this level of detail</p> <p>7 that I remember, but I would have to confirm</p> <p>8 that by looking at the paper. Do you want me</p> <p>9 to do that?</p> <p>10 Q Who was it who decided to use 5 milliliters</p> <p>11 of oxidated media in each file?</p> <p>12 A I don't remember. We discussed this test. I</p> <p>13 don't remember discussing where exactly that</p> <p>14 came from. I know -- I'm trying to find</p> <p>15 this.</p> <p>16 Okay. Is there a question? What was the</p> <p>17 question? I don't remember. I thought I</p> <p>18 answered it, but I will answer it again.</p> <p>19 Q Let me just ask the question again. Who</p> <p>20 decided to use approximately 5 milliliters s</p> <p>21 of oxidated media to be put in into each</p> <p>22 vial?</p> <p>23 A I know we discussed this, but I don't</p> <p>24 remember the details. We discussed all of</p> <p>25 these points, and I just don't remember that,</p>

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<p style="text-align: right;">Page 154</p> <p>1 any more details than that.</p> <p>2 Q The same number of samples of unstabilized</p> <p>3 polypropylene control were not used as the</p> <p>4 TVT; is that correct?</p> <p>5 A I need to look at the spreadsheet again.</p> <p>6 Polypropylene standard -- you say the same --</p> <p>7 why -- I don't see that. Where are you</p> <p>8 looking?</p> <p>9 Q I'm looking at the Excel file you pointed out</p> <p>10 at above PP standard. Let's just make sure.</p> <p>11 Is the PP standard, is that the unstabilized</p> <p>12 polypropylene control?</p> <p>13 A Yes. And to get back to one of your previous</p> <p>14 questions, the MSDS and the supplier for that</p> <p>15 material is here.</p> <p>16 Q And so for the unstabilized polypropylene</p> <p>17 control, there were only 15 samples, correct?</p> <p>18 A Oh, I see the top of the column, 15 samples.</p> <p>19 That's probably because it became oxidized</p> <p>20 more quickly. I don't -- so we only went out</p> <p>21 to four weeks with the -- because it became</p> <p>22 induced faster, the 15 samples. I don't know</p> <p>23 the answer to that now, what the number of</p> <p>24 replicates for each time point was. I can't</p> <p>25 tell from this table.</p>	<p style="text-align: right;">Page 156</p> <p>1 something that Dr. Dunn did?</p> <p>2 A I can't remember the details of that decision</p> <p>3 right now.</p> <p>4 Q Who made the decision to only use 15 samples</p> <p>5 of the unstabilized polypropylene but 36</p> <p>6 samples of the TVT?</p> <p>7 A I don't remember those details either.</p> <p>8 Q When you do statistical analyses comparing</p> <p>9 the unstabilized polypropylene to the TVT,</p> <p>10 don't you have to take into account</p> <p>11 differences in sample sizes and differences</p> <p>12 in the quantity of time points analyzed?</p> <p>13 A Yeah, for comparing between -- for comparing</p> <p>14 between groups, those factors would have to</p> <p>15 be taken into account, but I just don't</p> <p>16 remember the details of that study design.</p> <p>17 Q Who did the FTIR testing?</p> <p>18 A Dr. Dunn.</p> <p>19 Q He personally did it or did he have somebody</p> <p>20 else do it?</p> <p>21 A I believe he did it. But, again, it was done</p> <p>22 through his company, so I don't know the</p> <p>23 details of who actually did what</p> <p>24 measurements, but I believe he did it.</p> <p>25 Q Do you know where this FTIR machine was that</p>
<p style="text-align: right;">Page 155</p> <p>1 Q Why were there only 15 samples of the</p> <p>2 unstabilized polypropylene control, but 36</p> <p>3 samples of the TVT?</p> <p>4 A Well, one reason would be because we didn't</p> <p>5 do as many time points. We did four weeks,</p> <p>6 it looks like, instead of -- and I don't</p> <p>7 think that we did as much -- I spoke</p> <p>8 incorrectly. I think previously it appears</p> <p>9 that we actually had separate samples for XPS</p> <p>10 and FTIR, and it doesn't look like we had as</p> <p>11 many XPS samples. I would have to think</p> <p>12 about that.</p> <p>13 Q Do you know why you only analyzed the</p> <p>14 unstabilized polypropylene control out to</p> <p>15 four weeks, whereas you analyzed the TVT</p> <p>16 later?</p> <p>17 A It became induced faster, so the unstabilized</p> <p>18 control became induced between weeks three</p> <p>19 and four. So we didn't do as many time</p> <p>20 limits.</p> <p>21 Q You could have still tested it, though, at</p> <p>22 five and six weeks, right?</p> <p>23 A We could have.</p> <p>24 Q Did you make an affirmative decision not to</p> <p>25 test at four and five weeks or is that</p>	<p style="text-align: right;">Page 157</p> <p>1 was used in this test?</p> <p>2 A Yes. It's in his laboratory.</p> <p>3 Q So he used the Vanderbilt lab FTIR machine</p> <p>4 for the test?</p> <p>5 A Well, I would say he used the FTIR in his</p> <p>6 laboratory at Vanderbilt.</p> <p>7 Q Did he buy that FTIR machine?</p> <p>8 A He would have to speak to the details of</p> <p>9 that.</p> <p>10 Q I guess the question is -- you took issue</p> <p>11 with whether I asked you -- do you know who</p> <p>12 owns that FTIR machine? Is it Vanderbilt or</p> <p>13 Dr. Dunn or --</p> <p>14 A I don't know the details of that. When you</p> <p>15 said the Vanderbilt lab, that was, I thought,</p> <p>16 a little vague. I wanted to clarify that it</p> <p>17 was -- it's in his laboratory space that he</p> <p>18 has been assigned at Vanderbilt.</p> <p>19 Q Okay.</p> <p>20 A That's what I meant.</p> <p>21 Q All right. But it very well could be that</p> <p>22 that is a machine that is actually owned by</p> <p>23 Vanderbilt?</p> <p>24 A I don't know the details. As I said,</p> <p>25 Dr. Dunn has an agreement with the</p>

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<p>1 university. That's all I know. He would 2 have to speak as to the rest of it. 3 Q Now, the SEM analysis, whose SEM machine was 4 used? 5 A There is an SEM instrument and it's an 6 institutional resource. It's a shared 7 resource is perhaps a better way of saying 8 it, and so we pay for machine time. 9 Q Is it located at Vanderbilt? 10 A It is. 11 Q In what school? 12 A Well, it's an institute, so it's between 13 schools and the members of the school of 14 engineering, college of arts and science, 15 medicine. It's a shared resource. 16 Q It's not in Dr. Dunn's lab? 17 A No. 18 Q Physically where is it? Is it within a 19 building in the department of medicine? 20 Department of engineering? 21 A Again, it's a building that has shared space 22 between the college of arts and science and 23 the school of engineering. 24 Q Who did the SEM images? 25 A Again, it was Dr. Dunn's company. Whether he</p>	<p>1 expertise. She has a lot of experience with 2 it. 3 Q Is Dr. Rogers an expert for plaintiffs in 4 transvaginal mesh litigation that you're 5 aware of? 6 A Not to my knowledge. She was contracted by 7 Dr. Dunn to do the work. 8 Q Do you know how much she was paid by 9 Dr. Dunn? 10 A I don't know the details of that. Probably 11 the same as my arrangement, but I don't know. 12 Q Was she aware of Dr. Dunn's role as an expert 13 in transvaginal mesh litigation? 14 A Yes, she was, to my knowledge. 15 Q She is aware that Dr. Dunn is being paid by 16 attorneys for plaintiffs in transvaginal mesh 17 litigation? 18 A I believe she would. 19 Q So when she sat down to do this XPS analysis, 20 she knew that the money was coming from 21 plaintiffs' lawyers in transvaginal mesh 22 litigation? 23 A Yes, I believe she knew that. I haven't -- 24 I'm hesitating because I can't remember 25 explicitly discussing that with her, but I</p>
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<p>1 had an employee doing that, I don't know. He 2 was responsible for all of that. 3 Q The XPS machine that was used to look at the 4 sample, where is that machine? 5 A So that machine is also administered by the 6 institute I was referring to earlier. It's 7 housed in the laboratory of Professor Bridget 8 Rogers. So to clarify just for the record 9 one of the earlier questions about who else 10 at Vanderbilt was involved, Professor Bridget 11 Rogers is a professor, an associate professor 12 of chemical and biomolecular engineering, and 13 she did the XPS testing. 14 That slipped my mind earlier, I'm sorry, 15 until we talked about it now. 16 Q So Dr. Rogers was actually the one who did 17 the XPS testing on this single TVT retropubic 18 device and the unstabilized polypropylene 19 control? 20 A She did. 21 Q Were you there when she did the testing? 22 A No, but I don't need to be there when she -- 23 it's a -- she ran it and -- 24 Q Why didn't you do the XPS testing? 25 A That's Dr. Rogers' particular area of</p>	<p>1 believe based on conversations with Russell 2 that she knew she was being paid by 3 litigation. 4 Q Did Dr. Dunn have a conversation with 5 Dr. Rogers about doing this XPS testing? 6 A Yes. 7 Q Were you present at the time of that 8 conversation? 9 A For some of the conversations, we did discuss 10 it as a group with Professor Rogers. Was I 11 there for every conversation, I can't say 12 that I was. I did discuss this with 13 Professors Dunn and Rogers. 14 Q And what was said? 15 A Well, we discussed how to do the analysis, 16 what we were looking for, how we wanted to do 17 the experiment, and what the goal was. We 18 discussed the approach for the measurements. 19 Q Who paid for the SEM time? 20 A Again, I can't answer that -- oh, for the 21 SEM. I'm sorry. I believe that Dr. Dunn has 22 a sponsor research agreement through the 23 university in which he set up a cost center. 24 But, again, he has to speak to all of this. 25 I believe it was paid for by the litigation</p>

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<p style="text-align: right;">Page 162</p> <p>1 through a center number from the university. 2 Q What do you mean by center number? 3 A Well, when we do internal billing within the 4 university, we have cost centers associated 5 with different funding sources. So he would 6 have used the cost center associated with his 7 sponsored research agreement. But, again, I 8 am hesitant to go -- it's his project. I 9 don't know the details of that. 10 Q Who paid Dr. Rogers for her time? 11 A Dr. Dunn. She invoiced Dr. Dunn, and then 12 Dr. Dunn invoiced plaintiff's counsel. 13 Q How much did Dr. Rogers' invoice in 14 connection with this test that you're relying 15 on? 16 A I don't know the answer to that. 17 Q Do you know how much Dr. Dunn has invoiced in 18 connection with this test that you're relying 19 on? 20 A I haven't seen his invoices. I don't know. 21 Q Would it be based on your understanding more 22 than \$50,000 as an accurate prediction? 23 A I don't know. I can't put a number on it 24 because I didn't see the invoices. 25 Q For the use of the XPS machine, am I correct</p>	<p style="text-align: right;">Page 164</p> <p>1 Q These aren't the same pellets that are used 2 in the TVT device, correct? 3 A Not to my knowledge. 4 Q What is isotactic polypropylene? 5 A That is just a reference to the structure of 6 the polypropylene. Most polypropylene is 7 sold commercially. And my understanding is 8 isotactic is the most common isomer. I will 9 say to my knowledge that polypropylene used 10 to make Prolene is also isotactic, if that 11 helps. 12 Q Are you certain of that? 13 A Pretty certain. I believe that's the case. 14 Q Section 9 has different physical and chemical 15 properties of this unstabilized polypropylene 16 control? 17 A Section 9, yes. 18 Q Do you know if these properties are in any 19 way different than the polypropylene pellets 20 that are used in the TVT device? 21 A Could you ask that again? I didn't catch it. 22 Q Sure. 23 For the chemical and physical properties 24 of the unstabilized polypropylene control 25 that you used, are you aware if the</p>
<p style="text-align: right;">Page 163</p> <p>1 that someone would have to pay for that time 2 or usage as well? 3 A I don't know the details of that arrangement 4 with the XPS with Dr. Rogers. I can't speak 5 to that. 6 Q The unstabilized polypropylene control, is 7 that contained within the file that says 8 polypropylene standard MSDS? 9 A You were interested about the source? 10 Q Yes. 11 A Yes, I believe that it is, and I'm going to 12 look at it right now. So this is the file, 13 polypropylene standard MSDS, and I'm clicking 14 on this link. 15 Okay. This is an MSDS. I believe it is 16 the polypropylene standard. If you see the 17 ingredient, it says isotactic polypropylene 18 at 100 percent. So this would be the 19 unstabilized polypropylene control. It was 20 purchased from Scientific Polymer Products, 21 Incorporated, and that would be the MSDS for 22 that material. 23 Q And this is the pellets that you were talking 24 about? 25 A Yes.</p>	<p style="text-align: right;">Page 165</p> <p>1 properties are any different than the same 2 properties for the pellets that are 3 specifically used in the TVT device? 4 A These properties appear to me to be very 5 similar. If I'm looking at Sections 9 and 6 10, the melting point of 160 degrees. This 7 is the melting point I remember for Prolene 8 from some of the internal documents, the 9 saline water is negligible. 10 If we look at stability and reactivity, 11 it also says materials to avoid, oxidizing 12 materials. It looks very much like something 13 I would see for the MSDS for the 14 polypropylene used to make Prolene that I 15 saw. So to answer to your question, I would 16 say it looks similar to me. 17 Q And for the SEM test results that you -- 18 A Did you open the file? Is that where you 19 are? 20 Q Yeah, I was going to ask you. The SEM test 21 results you believe showed pitting and you 22 said peeling. Would those be found in that 23 folder PCT-168SEM? 24 A I'm looking. SEM, yes. 25 Did you have a question or --</p>

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<p style="text-align: right;">Page 166</p> <p>1 Q I am just trying to see, are the SEM images 2 that you referenced in that file PCT-168SEM? 3 A I'm looking at a file TVT five week SEM PDF. 4 I'm not sure what you're asking me. If you 5 can just ask me again what you're looking 6 for. 7 Q The particular SEM images that you referenced 8 that you be believed showed pitting or the 9 peeling? 10 A Yes. 11 MR. KUNTZ: I will object. But 12 go ahead. 13 A Okay. So I'm looking at this. I'm in this 14 SEM directory. I'm clicking On TVT five 15 weeks. There is a folder called TVT five 16 weeks, and I believe these are individual 17 files. And then I believe this file TVT SEM, 18 TVT five weeks SEM PDF, I believe that that 19 is the file I was talking about earlier. 20 So when I open this file, I see a number 21 of SEM images of PET that show that there is 22 a pitting and flaking on the surface of the 23 TVT. That's what I was describing earlier. 24 BY MR. SNELL: 25 Q On the second photo -- can you look at my</p>	<p style="text-align: right;">Page 168</p> <p>1 Q This does not show anything like that, 2 correct? 3 A We don't see the cracking because we did not 4 apply -- these materials are not under 5 tension. There is no residual strain. So in 6 the Anderson paper 1993, they prestressed the 7 materials. And when they did this -- and 8 they incubated them in an oxidative medium. 9 When they did this, they were able to see 10 environmental stress cracking. 11 We did not prestress the materials. 12 Again, the question was really to answer can 13 it oxidize. So without that mechanical 14 stress, we see more of these effects of 15 peeling and blistering. And this is 16 described in a number of papers to see 17 environmental stress cracking you need a 18 combination of three things. One is an 19 oxidative medium, the second is a material 20 that degrades in response to that medium, and 21 the third is mechanical stress. 22 So that -- there is no mechanical stress 23 in this experiment, which would be why I 24 don't believe we were seeing the transverse 25 cracking as noticed in Clave and other</p>
<p style="text-align: right;">Page 167</p> <p>1 computer? 2 A The second photo is called PCT168SEM007. 3 Q Yes, that's what I'm looking at. 4 A Okay. 5 Q And towards the middle, that's a fiber that 6 we're looking at? 7 A Yes, that's a specific fiber. 8 Q Take a look towards the middle at the bottom, 9 if you can look at what I'm looking at. 10 Right here. 11 A Yes. 12 Q Right above the times 400. 13 A Yes. 14 Q And then moving directly north in the middle 15 here. What is that? 16 A That looks to me like an area that I would 17 call degradation, where the surface is 18 changing. It looks like there is some 19 pitting and some residue, blistering perhaps. 20 That looks like an area of surface 21 degradation. 22 Q In the SEM photos that I've seen in the 23 literature, those typically show cracks 24 running horizontal, correct? 25 A That's right.</p>	<p style="text-align: right;">Page 169</p> <p>1 papers. 2 Q Isn't another just as plausible answer that 3 there is no proteins and biofilm on these 4 images? 5 A Not in my opinion. 6 Q Let me ask you, were proteins and biofilm 7 actually put on your samples of the TVT 8 device? 9 A So I want to be specific about this term 10 biofilm. Biofilm is a polysaccharide matrix. 11 It's deposited by bacteria. To me that's 12 different than protein absorption. And I'm 13 not aware of papers that are saying protein 14 absorption is causing cracking. I mean, but 15 the biofilm to me is the polysaccharide 16 matrix deposited by bacteria. 17 Protein absorption is something 18 different, but it -- I mean, the surface is 19 degrading here is what I see in response to 20 the chemical induction is how I interpret 21 these events. 22 Q There is no cracking in your photos of the 23 SEMs similar to those seen in the body as in 24 Clave and Costello and de Tayrac, correct? 25 A Again, there is no cracking here because</p>

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<p style="text-align: right;">Page 170</p> <p>1 these materials were not under any mechanical 2 stress. There was no force. They weren't 3 pre-strained like in the '93 Anderson paper. 4 This is a protocol that was used in the '97 5 Anderson paper to answer the question of 6 oxidation. We didn't have mechanical 7 strengths, and that's why we're not seeing 8 cracking. 9 Q You would agree that another plausible 10 explanation for why you don't see cracking is 11 there was no biofilm used in your testing? 12 MR. KUNTZ: Objection. 13 A I don't agree with that. 14 BY MR. SNELL: 15 Q Have you seen anywhere in the literature 16 during your analyses where cracking was seen 17 on an explant, and upon cleaning the explant, 18 it was determined that biofilm was the source 19 of the cracking? First of all, have you seen 20 that in the literature? 21 MR. KUNTZ: Objection. Go 22 ahead. 23 A I believe the paper you're talking about that 24 I've seen was -- and correct me if I'm 25 describing the wrong paper, but I have seen a</p>	<p style="text-align: right;">Page 172</p> <p>1 show the cracks. And then after they have 2 cleaned off the biofilm, you know, it was 3 clear that the filaments were fine? 4 A Yes, but I think this is a different 5 question. I agree with what that paper is 6 saying in that -- we can pull it up and look 7 at it again. I'm going on my memory, but I 8 think it was only 30 days. And I have done 9 these experiments myself. I've contaminated 10 scaffolds and placed them in -- I just 11 published a paper on this last year -- we 12 placed it in a bone defect. 13 We come back four weeks later, and we see 14 a biofilm, and it looks a lot like that 15 biofilm. And they clean it off, and, yeah, 16 there is no damage to the polypropylene 17 because it was only 30 days. It was a very 18 short period of time. And as we've been 19 discussing from Liebert and some of these 20 other papers, we wouldn't -- scientifically, 21 polypropylene would be induced at around 100 22 days. 23 So it's not too surprising to me that in 24 30 days, the polypropylene hasn't started to 25 crack yet. That's a very early time point.</p>
<p style="text-align: right;">Page 171</p> <p>1 paper where the mesh was challenged with 2 bacteria. We have a contaminated mesh. And 3 then the SEM images I saw -- this is only 30 4 days, and this SEM image showed what appeared 5 to be a biofilm, which I would expect, 6 because it was challenged with bacteria, and 7 that biofilm showed cracks. But it looked 8 like a biofilm. It didn't look like the SEM 9 images in Clave. And some of the other 10 explanted mesh papers don't look like 11 biofilms to me. 12 We can look at that paper. It's in my 13 reliance materials. I can look for it, but I 14 believe that's the paper you're referring to, 15 and I have considered that. I believe that's 16 a biofilm. And if you wash that biofilm off, 17 it goes away, and there is no damage to 18 underlying substrate, because it's only 30 19 days. And so these events may not have 20 started happening yet, because 30 days is a 21 relative short period of time. That's my 22 explanation of the paper that I believe 23 you're referring to. 24 Q It's the de Tayrac paper. You're aware of 25 that? There is actually images where they</p>	<p style="text-align: right;">Page 173</p> <p>1 That's the way I understand that paper. But, 2 again, I would be happy talk about it with 3 you, but that's my memory of that paper. 4 Q Do we know how much the Prolene polypropylene 5 is induced at 120 days? 6 A I think I know what you're getting at, but I 7 would like you to ask it a different way. 8 Induction time, it's an event, so we can't 9 say how much it's induced. We can say either 10 it's become induced or it has not. So are 11 you asking -- I guess I'm not sure what 12 you're asking. 13 Q What is the significance of induction? 14 A So it's described in many of my reliance 15 materials. But an induction -- just to think 16 of a plot, we see a small change in 17 properties. So it's oxidizing, because there 18 is adherent macrophages in giant cells, and 19 it's oxidizing. 20 And then we reach this point where the 21 reaction becomes autocatalytic, and there is 22 a very strong increase in the slope, kind of 23 like hockey-stick applied. And that change 24 in the slope, we refer to as the chemical 25 induction time. So it's an event.</p>

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<p style="text-align: right;">Page 174</p> <p>1 So to say how much it is induced, I'm -- 2 I'm trying to explain why I can't answer that 3 question. 4 Q When does that chemical induction time take 5 place with the Prolene polypropylene? 6 A We talked about this earlier. It's difficult 7 to -- when that happens in the body is going 8 to be affected by a number of factors. But 9 it's -- I think it's unlikely that that would 10 happen in 30 days. That's very early. And 11 that's why I explained the biofilm -- it 12 could happen maybe in some conditions in 30 13 days, but I don't believe in that experiment. 14 Q Is there a certain point in which it becomes 15 significant? 16 A What becomes significant? 17 Q This induction. 18 A Well, it's an event. So at induction, there 19 is dramatic changes in physical properties. 20 But embrittlement in these events can happen 21 even before induction. But, again, that 22 experiment is just -- they have this one -- 23 it only went out to 30 days, and I just don't 24 think they went far enough to see the stress 25 cracking.</p>	<p style="text-align: right;">Page 176</p> <p>1 Q Under PCT 168 XPS -- 2 A Oh, you're on the XPS now. 3 Q I'm in a Document 11062014 PCT 168 report. 4 A Are you looking at the XPS report? 5 Q Yes. This is actually from Bridget Rogers. 6 A Okay. I am pulling up the report. 7 Q On the second page, table one, it says 8 fraction of carbon atoms bonded in the RCOOH 9 and the CO configuration? 10 A Right. 11 Q What is that RCOOH? 12 A So RCOOH is the hydroperoxide group that's 13 formed when the polypropylene is oxidized. 14 It's an intermediate in that complex reaction 15 mechanism. 16 Q And what does it mean when there is zeros in 17 this table? 18 A So if it's a zero, that means that in that 19 particular spot she was looking at under the 20 microscope, there was no oxidized 21 polypropylene. In that particular spot, the 22 polypropylene had not been oxidized. And 23 then where we see the numbers is where we see 24 evidence of oxidation of the polypropylene. 25 Q What does the C equal sign --</p>
<p style="text-align: right;">Page 175</p> <p>1 Q I'm looking here, and there is a folder 2 called TVT six week SEM? 3 A Yes. 4 Q That would be the six-week images? 5 A Let me open that. Let me pull it up. I 6 think that is what it is, but -- yes, that 7 would be the six-week images. 8 Q Why were SEMs only done on some of the 9 samples? 10 A We were limited by the number of samples and 11 just the amount of time to get this work 12 done. And so we know that, as I was just 13 explaining, once we reach the induction time, 14 that we would expect to see these significant 15 physical changes, physical degradation. 16 And when the FTIR measurements told us 17 that it was induced between weeks four and 18 five, we did SEM images at week five, and 19 then compared to the pristine sample, because 20 we were comparing the period in which it's 21 become induced. We still have the samples, I 22 believe. 23 And I think we did this really out of 24 time constraints because there was so many 25 samples.</p>	<p style="text-align: right;">Page 177</p> <p>1 A That's a carbonyl bond. That's also a 2 reaction product. 3 Q Why is there supposedly a carbonyl bond in 4 sample two in one week? 5 A I'm not sure. 6 Q That makes no sense base on the literature 7 and data as you understand it, correct? 8 A I wouldn't say it makes no sense. I mean, it 9 could be that small regions of the 10 polypropylene are oxidized before they were 11 implanted. We have seen that in other 12 exemplars. It is possible that there is 13 oxidation on the mesh before it's even 14 implanted 15 Q Where would that oxidation come from on the 16 mesh? 17 A Thermal processing. When it's extruded and 18 processed at high temperatures, if those 19 antioxidants get depleted, it's not 20 surprising to me that you would see regions 21 -- we have seen it on exemplars. And I can't 22 say which meshes, but it's possible for the 23 mesh to be oxidized during processing. 24 Q Is it your opinion that this shows the TVT 25 mesh is thermally oxidized?</p>

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<p style="text-align: right;">Page 178</p> <p>1 A That's not what I'm saying. I'm saying that 2 that could be an explanation for why that 3 number is not zero. 4 Q Another explanation could be that her test is 5 just wrong, correct? 6 MR. KUNTZ: Objection. 7 A I wouldn't say it's just wrong. I would say 8 that when you look at the XPS as a whole, 9 it's consistent with the FTIR data. We see 10 regions of oxidation, and those numbers 11 generally increase with time. And that point 12 at one week -- yeah, there could be multiple 13 explanations for that. 14 BY MR. SNELL: 15 Q You would not expect to see a reading at one 16 week for the CO bond, correct? 17 A No, not if -- I mean, if it had regions of 18 oxidation, that could happen. It could have 19 been that in that particular measurement, she 20 was looking at a region that hadn't been 21 oxidized during processing. That can't be 22 ruled out. 23 Q Well, what are all the possible reasons why 24 you could find this CO finding in the second 25 TVT sample at week one, besides there could</p>	<p style="text-align: right;">Page 180</p> <p>1 A She said that's what she saw. She trusts her 2 methods. She stands by her methods. I'm not 3 shocked, because as I said, we have 4 sufficient oxidation in these meshes. The 5 exemplars, you open them out of the box, and 6 in some cases, we have seen oxidation. So 7 I'm not shocked by this. 8 Q Is it correct that one explanation could be 9 that something was wrong with her equipment 10 on that date, with the calibration or the 11 test methods she did on that particular 12 sample? 13 A It's a possibility, but an unlikely one. 14 Q Did you go back and look at any documents or 15 any log books or anything like that with 16 regard to what happened during that testing 17 on week one? 18 A We looked at -- Dr. Dunn and I and Dr. Rogers 19 reviewed a fair amount of the original data, 20 which she showed us the peaks in the XPS 21 spectra. 22 She has an algorithm for separating the 23 peaks, as described in her report, and that's 24 what she saw. And, again, this is looking 25 through a microscope at one small spot on the</p>
<p style="text-align: right;">Page 179</p> <p>1 be thermal oxidation that you're saying, I 2 guess? 3 Could her equipment not be calibrated or 4 running properly on that certain day? 5 A I think that is pretty unlikely. I think 6 that it could be that there was a region in 7 the mesh where the antioxidants had been 8 depleted and oxidized very quickly. It could 9 have happened during thermal oxidation. I 10 mean, those are some examples of what could 11 have happened. 12 But I don't think one data point that is 13 somewhat unexpected can be used to support 14 the notion that the method is flawed. You 15 can't rule out that the polypropylene wasn't 16 oxidized. You simply can't really explain 17 that data point. There is several possible 18 reasons, and none of them is terribly 19 conclusive. 20 Q Did you ask her why in the world, Doctor, are 21 you showing a positive finding in one week in 22 the CO bond in the second sample? 23 A We discussed it with her. 24 Q But what did she say about why that finding 25 was there at one week?</p>	<p style="text-align: right;">Page 181</p> <p>1 surface, and she saw this region where there 2 was some evidence of oxidation. 3 Q How small of a spot was that? 4 A I don't know the size of the spot, but I know 5 that she does this through a microscope. 6 Q Do you have an idea or a range? I mean, are 7 we talking about couple of microns or 1,000 8 microns? 9 A It's not -- you know, 1,000 microns would be 10 a millimeter. It's not that big. I don't 11 know the exact size of the spot. 12 Q There were no positive findings at week two, 13 correct? 14 A When you say positive, there was no evidence 15 -- none of the spots she looked at at week 16 two showed evidence of oxidation. That's the 17 way I would describe that. 18 Q And how do you explain that? 19 A Well, because she didn't see any evidence of 20 carbon-oxygen bonds at week two on any of the 21 spots she looked at. 22 Q On week three, there were only two findings 23 that were positive, correct? 24 A On week three, there were two spots where she 25 saw evidence of oxidation.</p>

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<p style="text-align: right;">Page 182</p> <p>1 Q On week three, second sample, it says 0.0088. 2 What does that mean? 3 A Let me look at her report in a little more 4 detail and make sure I answer that correctly. 5 So table one presents the fraction of 6 carbon atoms bonded in the RCOOH and RCO 7 configurations. So that would be -- the 8 fraction of carbon atoms for that would be 88 9 percent of the carbon atoms would bond to 10 that group is what she is reporting. 11 Q At week four, there was only one positive 12 finding, correct? 13 A Again, there was one spot that showed 14 evidence of oxidation. 15 Q Do you know why she didn't have a positive 16 finding in the second and third samples, but 17 had one the week before supposedly? 18 A I wouldn't say supposedly. Again, we are 19 looking at individual spots. And if you look 20 at the SEM images, you can see that there are 21 regions where there is degradation and then 22 regions where there is not. So there are 23 regions on the surface of this polypropylene 24 that are oxidized, and there are regions that 25 are not. And this is -- these are the number</p>	<p style="text-align: right;">Page 184</p> <p>1 induction at week five. 2 At week five, we see these remarkable -- 3 we see two spots, where now we have 4 essentially 50 percent of the carbon atoms 5 which she was looking at that are bound to 6 oxygen. We look at these data in week five. 7 The first two samples -- in the first sample 8 and the second sample, we see a dramatic 9 increase in, so that's what -- 10 Q In the third sample, there is no increase, 11 right? 12 A That's a region where -- well, there is some 13 carbonyl showing up, but that's a region 14 that was less oxidized than the other two. 15 That's the way I would interpret that. 16 Q The zero means no oxidation seen, correct? 17 A Well, I think we have to -- as Dr. Dunn has 18 testified previously, we need to consider 19 these two peaks together, because we are most 20 entered in looking at the fraction of carbons 21 that are bound to oxygen. That tells us 22 about oxidation. So we do see some carbonyl. 23 And there is no COOH group in that sample. 24 And, again, it is because we are looking 25 at different -- it depends on the spot that</p>
<p style="text-align: right;">Page 183</p> <p>1 of areas that that is what she observed. 2 Q You said you all looked at the raw data where 3 there were these peaks and things like that. 4 Where is that in this production? 5 A I don't see that in her report. We have that 6 data. I'm not sure where they are. 7 Q I'm going to request those. 8 A Yeah, and that's not going to be a difficult 9 thing to provide. 10 Q Has she done any statistical testing on that 11 XPS? 12 A No. And as I mentioned before, XPS is really 13 a qualitative tool to assess the structure of 14 the bonds. It's telling us that we see these 15 carbon-oxygen bonds that are indicative of 16 degradation. It is confirming the FTIR 17 findings. We are relying on the FTIR 18 findings for a more quantitative analysis 19 where we will run our statistical tests. 20 And it's because with XPS, we are looking 21 at different spots, and we can't distinguish 22 whether it's a degraded spot or whether it's 23 a non-degraded spot. What the XPS data 24 confirms is that there is regions of 25 degradation, and we can even see evidence of</p>	<p style="text-align: right;">Page 185</p> <p>1 you are looking at. 2 Q The CO, that's the carbon oxygen, the 3 carbonyl? 4 A The CO is a carbonyl bond. 5 Q Right. 6 So in the first sample, there was no 7 positive finding of the CO bond at weeks 8 four, five or six, correct? 9 A That's what it says, right. 10 Q How do you explain that finding? 11 A Again, I would look at this as adding 12 because these are -- you know, she is trying 13 to separate these two peaks using a 14 mathematical algorithm. And, you know, I 15 think we have to consider both numbers when 16 we talk about whether the surface is oxidized 17 or not. Both of those types of bonds can 18 occur on the surface. That is the way the 19 test works. 20 Q Even though there were, as she supposedly 21 records, RCOOH bonding, at weeks four, five 22 and six, there is no CO bonding. That's 23 fair, correct? 24 A That is what her analysis shows. 25 Q And there is zeros at even weeks five and</p>

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<p style="text-align: right;">Page 186</p> <p>1 six, correct?</p> <p>2 A Again, it depends on the spot you're looking</p> <p>3 at.</p> <p>4 Q Is it true or not, though, that there is</p> <p>5 zeros at weeks five and six?</p> <p>6 A Yeah, that's what I just said.</p> <p>7 Q And these numbers are not consistently</p> <p>8 showing oxidation across all samples at the</p> <p>9 same time point either; is that correct?</p> <p>10 A That's correct. And, again, that's because</p> <p>11 of where you are looking, just like the SEM</p> <p>12 images, not all regions are degraded.</p> <p>13 Q Or it could be because of issues in the test,</p> <p>14 correct?</p> <p>15 A Unlikely.</p> <p>16 Q But that's a possibility?</p> <p>17 A It's always a possibility. I mean, it's a</p> <p>18 possibility of any test.</p> <p>19 Q Have you done any analyses on cadaveric</p> <p>20 slings?</p> <p>21 A No. Cadaveric slings in my understanding</p> <p>22 aren't made of out of polypropylene.</p> <p>23 Q I think I would agree with that.</p> <p>24 But my question is simple. Have you done</p> <p>25 any testing on cadaveric slings?</p>	<p style="text-align: right;">Page 188</p> <p>1 Q Have you ever investigated the</p> <p>2 biocompatibility of porcine slings?</p> <p>3 A What do you mean by biocompatibility? That's</p> <p>4 a pretty controversial word. You mean in an</p> <p>5 ISO context or -- I'm not sure what you mean.</p> <p>6 Q I thought somewhere you talk about</p> <p>7 biocompatibility.</p> <p>8 A Where do I talk about biocompatibility? I</p> <p>9 want to be very careful with that word</p> <p>10 because it has a very evolving meaning.</p> <p>11 There is an ISO 10993 biocompatibility test</p> <p>12 that measures certain characteristics of the</p> <p>13 device. But biocompatibility really can be</p> <p>14 best understood in the context of the</p> <p>15 material and where it's being implanted. I'm</p> <p>16 not sure what you're asking about is the</p> <p>17 problem.</p> <p>18 Q Have you done any analysis on cadaveric</p> <p>19 slings for incontinence? Meaning, have you</p> <p>20 searched the literature to try to understand</p> <p>21 whether they degrade, whether they remodel,</p> <p>22 anything like that?</p> <p>23 A I have looked at that some, but not -- my</p> <p>24 understanding is that there is this Burch</p> <p>25 procedure where they can use autograft, I'm</p>
<p style="text-align: right;">Page 187</p> <p>1 A No. Why would I?</p> <p>2 Q I'm just asking.</p> <p>3 A Okay.</p> <p>4 Q You're reading too much into my question.</p> <p>5 A It's just this kind of came out of no where.</p> <p>6 Q Have you ever done any testing on biologic</p> <p>7 slings?</p> <p>8 MR. KUNTZ: Don't do this.</p> <p>9 MR. SNELL: I'm going to come</p> <p>10 back to it, I'm sure.</p> <p>11 BY MR. SNELL:</p> <p>12 Q Are you aware that biologic slings can</p> <p>13 degrade?</p> <p>14 A Okay. I would not use -- your terms are a</p> <p>15 little -- when you say biologic, are you</p> <p>16 talking about like the autograft or the</p> <p>17 allograft? What do you mean by biologic?</p> <p>18 Q You know like a pig sling.</p> <p>19 A You're supposed to call that a xenograft. I</p> <p>20 don't know that I would use the word degrade.</p> <p>21 I would prefer to use a word like remodel.</p> <p>22 It's reabsorbed, you know, so the old tissue</p> <p>23 in the xenograft is absorbed, and then new</p> <p>24 tissue is deposited by it. That's my</p> <p>25 understanding of what you're saying, I think.</p>	<p style="text-align: right;">Page 189</p> <p>1 aware of that, where they harvest autograft,</p> <p>2 There is the Lynn paper that talks about</p> <p>3 harvesting autograft and then implanting that</p> <p>4 as a sling. I'm less familiar with the</p> <p>5 allograft and xenograft models. I don't know</p> <p>6 where you would get allograft for something</p> <p>7 like this.</p> <p>8 But you're saying that there is a pig</p> <p>9 xenograft --</p> <p>10 Q Sling.</p> <p>11 A I'm not so familiar with that.</p> <p>12 Q Okay. Have you have done any research or</p> <p>13 seen any literature that specifically looks</p> <p>14 at polypropylene slings and determines that</p> <p>15 they did not degrade?</p> <p>16 A Again, I would like to be careful about this</p> <p>17 word degrade, so I'm going to answer your</p> <p>18 question as best as I can. I have seen</p> <p>19 papers that report findings that the sling</p> <p>20 does not degrade.</p> <p>21 There is a paper by Professor Dmochowski</p> <p>22 at Vanderbilt, he is a co-author on this</p> <p>23 paper where they looked at -- but they didn't</p> <p>24 use the types of techniques we're talking</p> <p>25 about. My understanding of this paper is</p>

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<p>1 degradation was assessed by a pathologist 2 from an H&E stained section. And it's not 3 clear to me that you would be able to see 4 degradation with a method like this unless it 5 were really bad. 6 So I'm aware of those papers, and I have 7 read them, and I have considered those views. 8 My concern is that they don't always use 9 these same techniques. 10 Q What doctor was that? Was that a doctor? 11 A Yes. He's a urologist at Vanderbilt. 12 Q Dmochowski? 13 A Dmochowski. That's who I'm talking about. 14 And I think you know him. 15 Q Any other papers? 16 A That's the one that comes to mind. I think 17 there are others too, but that is the one 18 that comes to mind. I mean, there is these 19 Nelson studies and these other papers, but, 20 again, they're not specifically looking -- 21 they may report that there is no degradation, 22 but when you read the paper, it's -- well, 23 in this case, they do patient surveys. 24 So how are you going to know that the 25 mesh degraded if you're just talking to</p>	<p>1 supports these opinions, but it doesn't 2 change them. 3 So if we look at opinion three -- and we 4 talked about this, but if we look at opinion 5 three, the antioxidants do not eliminate 6 degradation, and they do not guard 7 indefinitely against oxidative -- this is -- 8 the testing is relevant to this opinion. But 9 other than that -- again, it's the same 10 opinion. I'm just saying that the testing 11 further supports it. It doesn't change the 12 opinion. 13 Q The testing you're referring to is the 14 testing that we've been looking at? 15 A That we've just discussed, yeah. 16 Q And that's pertinent to opinion number three 17 about the antioxidants? 18 A I would say it's really pertinent to all 19 five, but most specifically of opinion three 20 I would say. Opinion six, I think, is 21 similar. I did talk in Huskey about 22 Ethicon's internal documents -- I'm referring 23 to oxidative degradation. 24 Q Which document are you talking about there? 25 A There is the Guidon study, the eight-year</p>
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<p>1 someone in a survey. So I'm aware that those 2 papers are out there, and I have a read a 3 number of them. 4 MR. SNELL: We are going to mark 5 your summary of opinions as the next exhibit. 6 (Deposition Exhibit No. 4 was 7 marked for identification.) 8 BY MR. SNELL: 9 Q So as we go through your opinions -- and just 10 to perhaps save us a little time, these are 11 the similar or the same opinions that you had 12 at the Huskey case, correct? 13 A Yes, most of them are. If it would help, I 14 can distinguish which opinions have been 15 modified or are different since Huskey. 16 Q Yes, that would be great. 17 Let me ask you to look at the exhibit we 18 marked for your summary of opinions in 19 Mrs. Perry's case, and tell us if the 20 opinions have been changed or added or 21 modified as compared to your Huskey opinion. 22 A So I believe opinions one, and two, and 23 three, four, five, those five opinions are 24 very similar to Huskey. What I would say is 25 new is the testing that we did further</p>	<p>1 explanted suture study. There is some other 2 -- the dog study even shows evidence of 3 degradation. Those are the two that come to 4 mind. 5 There is some comments in those reports 6 about scraping off material that appeared to 7 be degraded polypropylene on the basis of its 8 melting point and appearance, and 9 environmental stress cracking in the sutures. 10 All of that was discussed in Huskey. 11 Q In the Guidon eight-year explant suture study 12 that you referenced, when did those findings 13 of dyspareunia show? 14 A When did those findings of dyspareunia -- see 15 that. You're being cheeky now. 16 Q Yeah. 17 In the Guidon finger explant suture, 18 that's the vascular graft? 19 A That's right. 20 Q All right. At what point did the positive 21 findings that you relied on show up on that 22 study? 23 A So it was the eight-year time point where the 24 surface cracking became -- I think there was 25 some cracking observed at earlier time</p>

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<p style="text-align: right;">Page 194</p> <p>1 points, but in eight years, I remember it 2 being very severe. 3 Q And the dog study, at what point in time did 4 any of those findings become significant? 5 A I would have to look at the documents again, 6 but my latest review of them, it was -- what 7 I remember is the conclusion from the study 8 is that the cracking became worse with time, 9 up to seven years. Again, that was all 10 discussed in Huskey. 11 Q I didn't see that. I don't know if you 12 focused on the timing. 13 A Okay. Well, I just read this last night when 14 I was preparing, and I remember some 15 statements saying that the cracking appeared 16 to get worse. We can pull it up if you want 17 to talk about it. 18 Q Yes, let's just pull it up. I just want to 19 understand what you're talking about. 20 It would be under reliance documents? 21 A I believe it would be. 22 Q Do you remember how you had it labeled? 23 MR. KUNTZ: Do you want to ask 24 some questions about it? 25 MR. SNELL: Yes, just that one</p>	<p style="text-align: right;">Page 196</p> <p>1 point. Now, I'm looking at the seven year 2 time point. And the conclusions I am reading 3 here, the seven-year in vivo results 4 generally substantiated the five-year 5 findings, degradation in Prolene is still 6 increasing. 7 So the way I interpret this is from year 8 five to year seven, the degradation is 9 progressing, but I don't see any SEM images 10 here. 11 Q Do you know from that study when the cracking 12 first appeared, besides in five years? 13 A A few time points I have is five years and 14 seven years is what's shown in this study. 15 And then the fact that it got worse from year 16 five to year seven, and that's what is 17 reported in this study. And that's what I am 18 relying on for this opinion. 19 Q That study doesn't establish that the 20 cracking was there at, say, three years? 21 A It doesn't establish it was there at three 22 years because there was no three-year time 23 point. 24 Q All you know is that at five years, two out 25 of the overall sample had some cracking?</p>
<p style="text-align: right;">Page 195</p> <p>1 question about the time point. 2 MR. KUNTZ: You can use my copy, 3 but I don't want it marked as an exhibit. It 4 has highlights on it. I mean, just to speed 5 things up. 6 MR. SNELL: That's fine. 7 (Off-the-record discussion.) 8 BY MR. SNELL: 9 Q Okay. Go ahead. 10 A I'm just going to give you some points here. 11 So there is -- my understanding is that this 12 dog study was designed to be a ten-year 13 study. There was a five-year report that was 14 issued. In five years, two out of the seven 15 Prolene explants revealed cracking in five 16 years. And then there is some SEM images 17 here that show those explants, and I can see 18 the cracking that they're referring to in two 19 of those explants. 20 I would say that at least in the image I 21 have it's difficult to tell, but it looks 22 like there is a third one that might be 23 showing some evidence as well. This is what 24 I can see in these micrographs that are not 25 terribly clear. That was the five-year time</p>	<p style="text-align: right;">Page 197</p> <p>1 A That's right. 2 Q So you were looking at your list of opinions, 3 and you had talked about number six. And 4 number seven? 5 A So number seven, Ethicon ignored the warning 6 contained in the MSDS for the polypropylene 7 use in its products. It says the strong 8 oxidizing agents, like peroxides, are 9 incompatible with the polypropylene to the 10 detriment of patients implanted with the 11 mesh. So the MSDS warns that polypropylene 12 is sensitive to oxidation. 13 Again, our testing plays into this 14 because our testing has shown that even with 15 the antioxidants, it can oxidize. They don't 16 protect it forever, as I've wrote in opinion 17 three. And this is a detriment to patients 18 implanted with the mesh for two reasons. 19 One is, we've seen that oxidation 20 degradation can lead to embrittlement, pain, 21 and complications, as I have testified, with 22 Costello and Clave and Huskey in previous 23 testimony, and it increases the risk. It's 24 unpredictable, so it increases the risk to 25 the patients. It's a risk that they have to</p>

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<p style="text-align: right;">Page 198</p> <p>1 live with for their entire lives because the 2 device is there. 3 And as long as it's there, it's going to 4 be -- this reaction is ongoing. That's 5 opinion five. And it's important that the 6 antioxidants don't protect it forever. 7 Q That's basically the same as what you 8 expressed in Huskey? 9 A I believe it is. I just wanted to qualify 10 that I do believe that the testing data has 11 some impact on that opinion, and we've been 12 discussing that. But it's a similar opinion 13 to that held in Huskey. 14 Q What about number eight? 15 A Number eight, I think, is also similar to 16 Huskey. 17 Q In Huskey, as I recall it -- I mean, the 18 primary studies and documents that you 19 referred to and relied upon were the dog 20 study, the vascular suture graft study, 21 Clave, Costello? 22 A Yes. 23 Q The other one you mentioned today, Liebert, 24 is that another one that is important to your 25 opinions?</p>	<p style="text-align: right;">Page 200</p> <p>1 provide evidence of oxidation and degradation 2 and conclude that that contributed to the 3 embrittlement of the mesh. That could be 4 done. I did not do that in this case. I 5 didn't have the materials, but I don't want 6 to -- I would say from -- I don't -- maybe to 7 give you a better answer, I am not reviewing 8 medical records and -- 9 Q You're not doing a differential diagnoses and 10 drawing causal relationship inferences? 11 A Not in this case, no. 12 Q Nor in general, correct? 13 A I have testified that -- again, I saw 14 evidence of myeloperoxidase, which was 15 evidenced to me that these oxidative 16 processes are ongoing. That would lead to 17 changes in the polypropylene. So in terms of 18 -- you had a question? 19 Q The myeloperoxidase is not something you have 20 done on an Ethicon mesh? 21 A That's correct. 22 Q It's not something you have done on an 23 explant from an Ethicon patient to your 24 knowledge? 25 A To my knowledge. It may be in</p>
<p style="text-align: right;">Page 199</p> <p>1 A Yes, all of those studies that we've 2 discussed. 3 Q Okay. 4 MR. KUNTZ: I'm just going to 5 object. We have provided everything to you 6 he has relied on. It's not a memory test to 7 point out every single document, but I think 8 I understand your question. 9 A I testified that on those at Huskey, and my 10 opinion has not changed in that regard. 11 BY MR. SNELL: 12 Q And so I'm not going to recover those things 13 with you. 14 A That would be great. 15 Q You're not offering any medical or clinical 16 opinions with regard to Mrs. Perry at all; is 17 that correct? 18 A That's correct. 19 Q That would be totally outside your expertise, 20 correct? 21 A Medical and -- 22 Q Clinical? 23 A Medical and clinical? Just for the record, I 24 would not say it would be outside my 25 expertise to test the explanted mesh and</p>	<p style="text-align: right;">Page 201</p> <p>1 Dr. Iakovlev's, but I don't know. 2 Q And you understand that doctors are the ones 3 who actually do differential diagnoses and 4 draw conclusions about what complications 5 patients have? 6 A Could you explain differential diagnosis, 7 please? 8 Q Let me ask you, do you know what a 9 differential diagnosis is? 10 A Not precisely, I don't think. So I suppose I 11 wouldn't do that. I mean, it sounds like a 12 medical term to me. 13 Q Opinion number nine, explain that opinion to 14 me. Clearly, this is different. 15 A So after reviewing all of the Ethicon 16 documents and some published papers, my 17 conclusion was that this TVT Abbrevo mesh is 18 stiffer. There are several e-mails from 19 inventors of the mesh, such as Dr. Della 20 Valle, Dr. Nelson, that observed this 21 increase in stiffness, complained about an 22 increase in complications, asserted that this 23 mesh was different, and you could not rely 24 upon TVT machine-cut mesh data to support the 25 notion that TVT Abbrevo is the same.</p>

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<p>1 I reviewed mechanical testing done by 2 Ethicon, and an effort by Dr. Kammerer, I 3 believe, who is a fellow at Ethicon, who 4 basically replotted some of those data and 5 argued from Lynn that the mesh is subject to 6 the very small forces in this environment. 7 And when you compare over that very small 8 force range, he reported that the elongation, 9 the mechanical properties are the same. 10 I do not think this is a good way to 11 approach the problem. I think you would have 12 to consider as in the paper by Dietz, where 13 he went out to 80 percent, something -- okay. 14 So with the original Ethicon testing, they 15 went to 14 or 15-percent elongation. The 16 Dietz paper went out to maybe 80-percent 17 elongation. And at those higher elongations, 18 there are significant differences, stiffness 19 of TVT machine-cut and TVT laser-cut. 20 Dr. Kammerer only plotted the data over a 21 range of up to about a 4-percent strain 22 elongation, and that was just a very limited 23 range. He concluded that they were similar, 24 but I questioned the physiological relevance 25 of his approach in asserting that Lynn could</p>	<p>1 the decision-making process, not -- I did not 2 test these meshes mechanically. I'm making 3 this opinion on the basis of Ethicon 4 documents where they chose -- they 5 deliberately selected different ranges over 6 which to view the mechanical data. That's 7 what I'm questioning. 8 Q Well, I'm going to get to that. My focus is 9 on the e-mails. 10 Basically, what you did is you looked at 11 some e-mails that some people wrote, and you 12 adopted what they said, correct? 13 A Well, what do you mean I adopted what they 14 said? 15 Q Did you assume what was written on the paper 16 was accurate or true? 17 MR. KUNTZ: I'm just going to 18 object. 19 A I'm still not getting it. I mean, there was 20 statements by these surgeons that said it's 21 not the same. 22 BY MR. SNELL: 23 Q Okay. This is what I am just asking -- maybe 24 I'm making it too complex. 25 A Okay. I'm just not getting something.</p>
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<p>1 be used to support that assumption. That's 2 my opinion. 3 So the mesh, I believe, is stiffer. And 4 the decision was made to use the TVT 5 machine-cut data that is for the laser-cut 6 product even though it was different. That's 7 my opinion on number nine. 8 Q So you looked at the e-mails where 9 Dr. Della Valle or others may have written in 10 comments about the mesh being stiffer, 11 correct? 12 A I reviewed those e-mails, yeah. 13 Q So you read those the e-mails, and you 14 basically took as what they said to be as 15 true, right? 16 A I read as much as I could read. I read a lot 17 of documents. 18 Q How about this, what independent testing did 19 you do, if any, to confirm or not confirm 20 the supposed higher level of stiffness of 21 the mesh? 22 A Well, honestly I felt like I didn't need to 23 do independent testing. This is Ethicon data 24 that they relied on to make decisions. 25 That's what I'm criticizing. I'm criticizing</p>	<p>1 Q You saw some statements in an e-mail? 2 A Yes. 3 Q And you read them and what they meant to you, 4 right? 5 A Yeah. It seemed like a straight forward 6 statement. And I read it and that's what it 7 said, so I just -- 8 Q You didn't apply any further analysis to this 9 statement? 10 A What further analysis would I have applied? 11 It is just what it said. There were multiple 12 e-mails and there was an e-mail chain. I 13 read the question, and I read the response, 14 and I -- I mean, I did my best to review it, 15 but some of these comments were rather blunt 16 and direct, so it was -- 17 Q So you interpreted the statements without 18 doing any testing of their veracity or -- of 19 the points? 20 A I don't know how to test their veracity. It 21 just -- I mean, there were multiple 22 statements and there were multiple e-mails 23 that seemed to -- among Ethicon employees 24 that addressed this as a concern, so it just 25 wasn't one e-mail. It was -- there seemed to</p>

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<p style="text-align: right;">Page 206</p> <p>1 be many documents posing the question is TVT 2 machine-cut the same as TVT laser-cut Abbrevio 3 -- laser-cut versus the machine-cut. 4 There were numerous opinions and 5 documents going back and forth. Many were 6 questioning this decision. Others were 7 promoting it. There was -- it looked like a 8 fair amount of descension until Dr. Kammerer 9 did his analysis, and then what appeared to 10 me is that the decision was taken that these 11 products are the same. 12 So I read a lot of documents to form 13 this. I mean, if there is another one you 14 would like me to read, I would be happy to 15 read it. That's why I'm here. But this is 16 what I read, and this is what I saw, and this 17 is the opinion I came to. 18 Q I mean, these were basically e-mails written 19 by other people who wrote into the company. 20 And that's what you looked at, correct? 21 A Yes, but some were internally e-mails between 22 -- conversations between Ethicon employees 23 and Europe and North America and -- 24 Q Fair enough. 25 These are people writing e-mails to other</p>	<p style="text-align: right;">Page 208</p> <p>1 A That's the difference -- to my understanding, 2 that's the only difference in how they are 3 manufactured, but that could introduce 4 differences -- well, okay. 5 Q But they are the same in that respect, 6 correct? 7 A The same in what respect? 8 Q That they are the same up until the point 9 when they decide to cut the edges of the mesh 10 either mechanically or they do it with 11 laser, correct? 12 A I understand, yeah. 13 Q Is that correct? 14 A I believe so. I mean, I don't have the 15 details of how these are -- 16 Q So if we have two pieces of mesh, this is 17 mechanical, this is laser, is there any 18 difference in the mesh that is running down 19 the middle? 20 A I don't know. That has not been tested. All 21 I can say is that they are cut differently. 22 What affect that has on the mesh in the 23 middle, I don't know that that's been tested. 24 Q They are knitted the same, right? 25 A Yeah, but that cutting operation could change</p>
<p style="text-align: right;">Page 207</p> <p>1 people, correct? 2 A Yes. 3 Q The laser-cut and the mechanical cut mesh, 4 they are the same mesh, correct? 5 MR. KUNTZ: Objection. 6 A I would say they are cut from the same 7 Prolene mesh, but I would not say that they 8 are the same mesh. One has cut edges with a 9 machine, the other has a cut with a laser. 10 That's not the same to me. But if you want 11 to say they're prepared from the same source 12 mesh, I believe that's correct. 13 BY MR. SNELL: 14 Q Both of the meshes are made of the same 15 Prolene polypropylene, correct? 16 A That's my understanding. 17 Q And it's the same mesh that goes through all 18 of the same extrusion and manufacturing 19 processes up until the point when it's cut to 20 your understanding, correct? 21 A That's my understanding. 22 Q Right. 23 The only difference is the edges of the 24 strip of tape, one is cut mechanically and 25 one is cut with a laser, correct?</p>	<p style="text-align: right;">Page 209</p> <p>1 something. I just don't know and it's not 2 been looked at. 3 Q Well, Dr. Kammerer looked at it, right? 4 A No. Dr. Kammerer, I don't believe he 5 actually did any testing. I believe Dr. 6 Kammerer took data from previous experiments 7 and replotted them over a different range of 8 elongation. That's what I believe he did 9 from the documents I saw. 10 I didn't see -- all I saw in his report 11 was that he noted that he was using data from 12 other reports. I didn't see like he actually 13 did do measurements. That was my 14 understanding. 15 Q The elongation of the mesh, the 16 mechanically-cut and the laser-cut, were the 17 same at out to I believe it was 5 percent. 18 Do you have the document? 19 A It would help if we had the document. I was 20 going on my memory. I believe it was 4 21 percent maybe. It was not very many. I 22 believe it was 4 percent. It would help if 23 we had it. I don't know if it's on the disk 24 or, I mean, how easy it would be to find. 25 Q It will be on there. I'm sure if you'd look</p>

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<p style="text-align: right;">Page 210</p> <p>1 at it, it's on there.</p> <p>2 MR. KUNTZ: What are you looking</p> <p>3 for again?</p> <p>4 MR. SNELL: Kammerer's paper,</p> <p>5 the elongation testing.</p> <p>6 MR. KUNTZ: Which one?</p> <p>7 MR. SNELL: The analysis he did</p> <p>8 on elongation of the laser-cut versus the</p> <p>9 mechanical-cut. I want him to be able to</p> <p>10 look at it.</p> <p>11 (Off-the-record discussion.)</p> <p>12 BY MR. SNELL:</p> <p>13 Q Have you ever tested the forces in the</p> <p>14 pelvis?</p> <p>15 A No, I have not.</p> <p>16 Q What is your basis for saying that the</p> <p>17 reliance on the Lynn period paper is wrong?</p> <p>18 A Okay. So there is another -- okay. There is</p> <p>19 another e-mail by Dr. Kammerer, where he</p> <p>20 comments that the elongation on the mesh</p> <p>21 could be as high as 50 percent when it is</p> <p>22 implanted. And, obviously, if the mesh is</p> <p>23 elongated when it's implanted, that's going</p> <p>24 to move you down the force-distance curve.</p> <p>25 And the other point about Lynn is that</p>	<p style="text-align: right;">Page 212</p> <p>1 Does that make sense?</p> <p>2 Q This is the sling under the urethra, correct</p> <p>3 A Yeah.</p> <p>4 Q Do you know the size of the urethra?</p> <p>5 A Probably pretty small.</p> <p>6 Q So that low number, that small number -- do</p> <p>7 you understand that? Do you know whether</p> <p>8 that is consistent or inconsistent with basic</p> <p>9 anatomy and physiology of the urethra, in the</p> <p>10 support structures lying underneath the</p> <p>11 urethra?</p> <p>12 A It just seems to me that the sling in that</p> <p>13 study is different from the slings that are</p> <p>14 being used as the TVT. It's placed</p> <p>15 differently. I just don't know that you can</p> <p>16 make that same extrapolation, that the force</p> <p>17 on that autograft sling when somebody coughs</p> <p>18 is the same. It just seems --</p> <p>19 Q Do you know that you can't? I mean, have you</p> <p>20 done any testing or done any research that</p> <p>21 ever shows that one cannot do that?</p> <p>22 MR. KUNTZ: Objection. From</p> <p>23 what he has already said? From what Kammerer</p> <p>24 has already said? I just want to make sure</p> <p>25 we're clear.</p>
<p style="text-align: right;">Page 211</p> <p>1 what Lynn was really measuring was a</p> <p>2 differential force. So Lynn was measuring --</p> <p>3 so the patients were grafted with this what</p> <p>4 looked like the autograft fascia sling, and</p> <p>5 he was measuring the force when they cough</p> <p>6 with a full or empty bladder. That is a</p> <p>7 differential force. You don't know what the</p> <p>8 initial force or tension of the elongation of</p> <p>9 that sling was.</p> <p>10 And the differential forces that he was</p> <p>11 measuring were so small. They are something</p> <p>12 in the range of .1 to .2 pounds. I mean,</p> <p>13 that's like taking the meat patty from a</p> <p>14 junior cheeseburger and hanging it on -- I</p> <p>15 mean, we are talking forces that are really</p> <p>16 small. And that's a differential force on a</p> <p>17 sling when somebody coughs.</p> <p>18 It just doesn't seem very plausible to</p> <p>19 me. It's a very small force. If the sling</p> <p>20 is elongated up to 50 percent, when it's --</p> <p>21 then it's got some strain, and you don't know</p> <p>22 what that is. But that's going to make the</p> <p>23 stiffness higher if you're moving down that</p> <p>24 force-stiffness curve. That's what I'm</p> <p>25 saying.</p>	<p style="text-align: right;">Page 213</p> <p>1 MR. SNELL: No, I'm asking him.</p> <p>2 He says he doesn't know. Well, what I'm</p> <p>3 asking you is --</p> <p>4 MR. KUNTZ: He just referred to</p> <p>5 Ethicon's own document, where Gene Kammerer</p> <p>6 said it was different. Besides that?</p> <p>7 MR. SNELL: No, he didn't.</p> <p>8 MR. KUNTZ: Yeah, he did. He</p> <p>9 said his e-mail -- yes, he said exactly that.</p> <p>10 And now you're trying to say that he didn't.</p> <p>11 A I'm saying that Dr. Kammerer said that when</p> <p>12 you implant a sling, it can elongate as much</p> <p>13 as 50 percent. And 4 percent -- I mean, I've</p> <p>14 seen these slings. For 4 percent, that's</p> <p>15 like -- 4-percent elongation is like folding</p> <p>16 it out of the box. I mean, it's such a small</p> <p>17 amount.</p> <p>18 When you install it, it could be 40 or</p> <p>19 50-percent strain, and that moves you much</p> <p>20 further down that stress-strain curve where</p> <p>21 these materials become very, very different.</p> <p>22 That is Dr. Kammerer's email. And then he</p> <p>23 takes this paper from Dr. Lynn that says,</p> <p>24 well, actually, the differential -- he</p> <p>25 doesn't even call it a differential force, so</p>

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<p style="text-align: right;">Page 214</p> <p>1 that's what it was, because he doesn't know 2 the initial force on that sling. 3 He just knows that when somebody coughs 4 and exerts an additional force, that force 5 was in the range of half a newton. 6 BY MR. SNELL: 7 Q How do you know what Dr. Kammerer knows? 8 A Well, that's what he wrote. 9 Q Well, you just testified that he didn't know 10 something. How do you know that? 11 A What did I say? I don't know what I said he 12 didn't know. I don't know. He said that 13 when you implant the sling, it can extend, 14 it can elongate as much as 50 percent. Well, 15 that's a lot more than 4 percent. 16 Q Do you know what that was in the context of 17 and what type of testing that was in the 18 context of? 19 A In my understanding of reading that e-mail, 20 that was in the context of the procedure, of 21 implanting the sling. 22 Q The 50-percent elongation testing you've seen 23 done, they didn't even have the sheath on the 24 mesh; is that correct? Do you know what I'm 25 talking about? Have you seen 50-percent</p>	<p style="text-align: right;">Page 216</p> <p>1 That's what he says in the report. 2 I mean, I can read from it if you want 3 to, but that's to me what he said. He used 4 Lynn to justify that half a newton of force. 5 Q Have you have read Dr. Kammerer's deposition? 6 A I can't remember. I don't know. I don't 7 remember anything specific from his 8 deposition. 9 Well, I would be interested to -- 10 Q You would be interested to what? 11 A No, I'm just -- 12 MR. KUNTZ: I would be 13 interested why we got that e-mail after his 14 depo, but we can take that up with somebody 15 else. 16 BY MR. SNELL: 17 Q Item number ten, I think this was something 18 that was in Huskey, but you tell me if I'm 19 wrong. 20 A There is an element to that. What's new here 21 would be referring to this laser-cut versus 22 machine-cut. I don't believe -- to my 23 knowledge, the studies that were done were 24 this mechanical testing that I was referring 25 to. There was a 14-day rabbit study where</p>
<p style="text-align: right;">Page 215</p> <p>1 elongation testing? 2 A I'm not talking about testing. In 3 Dr. Kammerer's e-mail, he talked about with 4 the meshes and the procedures he's observed, 5 the mesh can elongate up to 50 percent. That 6 was, I think, the language that he used. So 7 that tells me when it is being implanted, 8 it's elongating. It's no longer -- it's not 9 4 percent. I mean, he is saying it could be 10 up to 50 percent. That is a much bigger 11 number than meaning 4. So I'm questioning 12 how he got this -- he basically took this 13 number of 4-percent strain, which is very 14 low, so he could argue that -- that's what it 15 looks like, that he could argue that over 16 that very small strain that these meshes are, 17 in fact, the same. 18 Q That is your inference of what was going 19 through his head? 20 A That's what he said in this document. He 21 puts that number for Lynn out, and then he 22 goes to that stress strain curve, and he 23 plotted the data over that range that he felt 24 was physiologically relevant on the basis of 25 the findings from Lynn. That's what he did.</p>	<p style="text-align: right;">Page 217</p> <p>1 they were measuring the infiltration, and 2 they were measuring pull-out strength, but it 3 was a very short time point, only 14 days. 4 And then there were e-mails from some of 5 these clinicians saying that we can't -- you 6 just can't use TVT machine-cut clinical data 7 to support TVT machine-cut, the notion that 8 the TVT laser-cut would perform the same, 9 because the meshes are different. And I 10 don't think they did enough testing to 11 establish whether they were different or not. 12 I would have liked to have seen more testing 13 to establish that fact. 14 Q What testing was done? 15 A What testing was done? 16 Q That's you're aware of. 17 Well, let me back up. 18 A Okay. 19 Q Did you do a PubMed or any other kind of 20 search to see what clinical literature there 21 was on the Abbrevio or laser-cut and 22 mechanical-cut meshes? 23 A I think there is some study on TVTS, which is 24 a -- but that product is off the market now. 25 I was relying heavily on these Ethicon</p>

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<p style="text-align: right;">Page 218</p> <p>1 documents, what they did, and the conclusions 2 that they drew from the testing that they 3 did. And I just thought that it wasn't -- it 4 wasn't enough. It wasn't convincing from the 5 way that the whole Kammerer conclusions were 6 drawn to a 14-day rabbit test. There should 7 have been more preclinical testing. 8 I mean, why did they not file a new 9 510(k)? That could have been a relatively 10 straight forward thing to do. 11 But to my knowledge, they didn't even 12 file a new 510(k) for the laser-cut mesh. 13 They just said it's the same without really 14 enough testing to reach that conclusion. 15 There was a process change that was just made 16 and never really validated. That's what that 17 opinion was saying. 18 Q The e-mails from the clinicians, that's the 19 same ones we talked with about with regard to 20 opinion number nine? 21 A Yeah. 22 Q And the 14-day rabbit study? 23 A That's what I remember. I think there was a 24 14-day rabbit study. 25 Q Do you know if that is the type of study that</p>	<p style="text-align: right;">Page 220</p> <p>1 offer an opinion that a 510(k) should have 2 been filed for laser-cut? Because if you 3 are, I want you to tell me -- 4 A I know what you want me to tell you. 5 Q -- the regulations, and I want you to tell me 6 exactly what documents they should have 7 looked at. I want you to basically sit there 8 and be a regulatory expert. 9 A I get it. 10 MR. KUNTZ: He will not be 11 giving that opinion. 12 BY MR. SNELL: 13 Q Can you just tell me you're not going to give 14 that opinion and then I can move on? 15 A I'm upset about what was done. But so we can 16 move on, I'm not going to give that opinion 17 as a regulatory expert. There were just 18 things that concerned me, but I'm not going 19 -- okay. I will retract that. 20 MR. SNELL: Jeff, he is not 21 going to get up at trial -- 22 MR. KUNTZ: He's not going to 23 give a 510(k). 24 A I'm not giving a 510(k) opinion. 25 MR. KUNTZ: That's what you want</p>
<p style="text-align: right;">Page 219</p> <p>1 is normally done in the industry to assess 2 pull-out force? 3 A That was my understanding. 4 Q Have you have ever conducted that type of 5 study? 6 A I have not. And I think that answers one 7 question about pull-out force, but I don't 8 know that that addresses his question of 9 differences in stiffness between the mesh. 10 And then these clinicians are saying that 11 they are seeing more complications. So there 12 were clinical warnings coming back that this 13 -- that something seems different here. 14 Q Are you a regulatory expert, such that you 15 can cite to any regulations right now that 16 say that Ethicon should have filed a 510(k) 17 specific to laser-cut mesh? 18 A I'm not -- I have a working knowledge of FDA 19 approaches. 20 Q If you're going to offer an opinion about a 21 510(k) -- 22 A Let me think about it for a minute. I know 23 where you are going with this. I just -- 24 Let's see if we can work through this. 25 Q Well, my question is, are you going to try to</p>	<p style="text-align: right;">Page 221</p> <p>1 to know. 2 A I'm not giving a 510k opinion. 3 BY MR. SNELL: 4 Q Because that's a whole other issue. 5 A I know. 6 Q There is nothing in your disclosures that say 7 he is a regulatory expert and he's talking 8 510(k)'s. 9 A I just have enough knowledge of this that I 10 saw things that disturbed me, but I'm not 11 going to give that opinion as a 510(k) 12 expert. I will stick to what I told you. I 13 will reign myself in. You are provoking me a 14 little bit. I'm not frustrated. I'm just -- 15 Q You know what they say, some knowledge is 16 dangerous. 17 A I'm going to stay within the scope of my 18 opinions that are written here. 19 Q Thank you. I would like that. 20 Okay. Are there specific scientific 21 studies that Ethicon should have done that 22 you are going to say would have produced some 23 type of clinically or statistically 24 significant difference as between the meshes? 25 A I would have liked to see a longer term</p>

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<p style="text-align: right;">Page 222</p> <p>1 implantation test than just 14 days. I think 2 if there were differences in stiffness, you 3 might have seen it in 90 days, but even 4 longer periods would have been -- this mesh 5 could have been tested in preclinical models 6 more relevant to the vaginal wall. So there 7 is something new in my reliance materials. 8 There is an abstract by Deprest, 9 D-E-P-R-E-S-T. That was published in 2013. 10 It's in the reliance materials, where they 11 had a large animal model where they compared 12 mesh in the abdominal wall to mesh in the 13 vaginal wall, and they saw eightfold more 14 contraction in the vaginal wall. 15 So I think these studies could have been 16 done by Ethicon to assess these differences. 17 I think they could have interpreted their 18 own mechanical data more conservatively. We 19 already discussed that, so I don't want to 20 bring that up again, but those are the 21 studies. But more preclinical studies and a 22 more thoughtful evaluation of their own 23 mechanical data is what I would say. 24 Q You're not saying that Gene Kammerer, who has 25 got 40 years of experience, is incompetent,</p>	<p style="text-align: right;">Page 224</p> <p>1 model. I don't know. 2 Q Would it surprise you to learn that laser-cut 3 mesh has been tested in sheep? 4 A In what model? 5 Q The sheep model. 6 A You mean on a wall model? On a subcu model? 7 Where in the sheep was it tested? 8 Q I guess my question is, would it surprise you 9 if you learned that it was done? 10 A Would it surprise me? I know that there was 11 a lot of testing done. I wasn't aware of the 12 study that tested in the vaginal wall. If 13 it's a subcu test, then, again, that's a 14 different environment. The interesting 15 aspect of the Deprest study to me was that 16 they looked at differences -- which they 17 asked the question, is it different in the 18 abdominal wall versus the vaginal wall. 19 And I haven't seen a document that -- I 20 mean, I would be happy to look at it if 21 you've got one, but I haven't seen that. 22 Q This study by Deprest, how big of a size of a 23 mesh was implanted? Do you know? 24 A I can't remember the details from that. It's 25 in the abstract. I don't know.</p>
<p style="text-align: right;">Page 223</p> <p>1 you just disagree with -- let me just finish. 2 You're not saying he is incompetent, you just 3 disagree with what he did? 4 A He might be too confident. What he did was 5 -- I don't like it. I don't like the way 6 that he handled the mechanical data to say 7 that everything was the same. I think that 8 was a flawed approach. I'm not saying he is 9 incompetent. I don't like the way he 10 approached that problem. I shouldn't say 11 don't like. I disagree with it. 12 Q But you have not conducted any independent 13 testing or analyses that would show what he 14 did was incorrect? 15 A I have not done any other testing. I was 16 relying on Ethicon documents at the time of 17 testing. 18 Q This Deprest 2013 paper, what type of animal 19 model was that? Was that a pig? 20 A It was a sheep. It is an abstract, I 21 believe, in the IUGA meeting in 2013. It's 22 in the reliance materials. That's new. 23 Q Do you know whether the laser-cut mesh has 24 ever been subjected to testing in a sheep? 25 A I don't know if there was testing in that</p>	<p style="text-align: right;">Page 225</p> <p>1 Q Do you know how they implanted it in the 2 vaginal wall? 3 A I can't remember how they did that. 4 Q It wasn't a sling put between the vagina and 5 the urethra? 6 A I don't believe it was a sling. I believe it 7 was more -- I just would have to look at it 8 again to remember it, but I don't believe it 9 was a sling. I think they implanted the 10 piece of mesh, but I can't remember the 11 details of how they did that. 12 Q Do you know when was a sheep model where 13 implantation in the sheep's vagina was first 14 perfected? 15 A I really don't understand. You mean as a 16 sling or you mean as like an implant? I'm 17 not sure what you mean. 18 Q As a model. Usually animal models, right, 19 you just don't come up with some theory and 20 do the model. Don't you have to test models 21 before you actually do them? 22 A Yeah. I mean, I work with colleagues where 23 we design new models for bone healing. 24 Q Is there a way to validate models? I guess 25 that's what -- I'm kind of getting towards,</p>

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<p style="text-align: right;">Page 226</p> <p>1 that area.</p> <p>2 A Yes. So if you want to validate a functional</p> <p>3 model, that's a different question. I think</p> <p>4 what they did in this study is they just</p> <p>5 implanted it adjacent to the tissue. I don't</p> <p>6 think it was intended to be a functional</p> <p>7 sling model.</p> <p>8 They were just asking the question, well,</p> <p>9 if I implant it here at the hernia abdominal</p> <p>10 wall versus here in the vaginal wall, do I</p> <p>11 see differences in cellular infiltration and</p> <p>12 contraction and those kinds -- it wasn't a --</p> <p>13 this abdominal wall model has been around for</p> <p>14 a while, right. So I think what they did</p> <p>15 that was different is they implanted it in</p> <p>16 the vaginal wall as well.</p> <p>17 Q It wasn't validated, though, as between the</p> <p>18 vaginal wall of the sheep and the abdominal</p> <p>19 wall of the sheep?</p> <p>20 A I don't know what you mean by validated.</p> <p>21 When I think of validation, that's like a</p> <p>22 functional model that you have to validate to</p> <p>23 make, so if you wanted to make a sheep sling</p> <p>24 model, you would have to validate that. I</p> <p>25 understand that, but I don't think that that</p>	<p style="text-align: right;">Page 228</p> <p>1 what I've found. I haven't -- well, I have</p> <p>2 looked. That's what I know right now.</p> <p>3 Q So have we discussed ten?</p> <p>4 A I don't have anything to add to ten.</p> <p>5 Q And 11 is similar to number ten -- or how is</p> <p>6 that different from anything you talked about</p> <p>7 in Huskey?</p> <p>8 A Let me read it for a minute.</p> <p>9 Q Sure.</p> <p>10 A I think the point in 11 is that when I say</p> <p>11 did not consider -- I think there is a lot of</p> <p>12 overlap with Huskey. They do not consider</p> <p>13 principles of biomaterial science by not</p> <p>14 testing it in an oxidative environment using</p> <p>15 a known test that was known since the early</p> <p>16 90's. Even though they knew and from their</p> <p>17 own studies, they saw evidence of oxidation</p> <p>18 and degradation, they never tested it.</p> <p>19 So to me, biomaterial science, if I know</p> <p>20 something is susceptible to oxidation, I need</p> <p>21 to test that and assess it. And I guess what</p> <p>22 would be new here is that, you know, we have</p> <p>23 tested that. In one exemplar of TVT mesh, we</p> <p>24 found that it can't oxidize. And that test</p> <p>25 could have been done by Ethicon. That is</p>
<p style="text-align: right;">Page 227</p> <p>1 is what they did.</p> <p>2 Q This wasn't a validated sheep model study?</p> <p>3 A I would say it wasn't a validated sling</p> <p>4 model. They weren't modeling the sling in</p> <p>5 the sheep and trying to draw some conclusion</p> <p>6 about how the sling would act in a human. I</p> <p>7 think they were just asking a question, how</p> <p>8 would this mesh infiltrate in these two</p> <p>9 different environments. That's what that</p> <p>10 model was, which I think is a legitimate</p> <p>11 thing to do.</p> <p>12 People have been implanting -- there is a</p> <p>13 number of rat abdominal wall models in other</p> <p>14 rodents and large animals. I don't think</p> <p>15 that is a -- I think that is a good approach.</p> <p>16 Q Have you ever seen it done before,</p> <p>17 implantation of mesh in a sheep or a large</p> <p>18 animal's vagina?</p> <p>19 A That's the first I have seen it, but there</p> <p>20 may be other studies.</p> <p>21 Q Did you do any investigation to see whether</p> <p>22 the findings were consistent or inconsistent</p> <p>23 with other testing or whether anyone had</p> <p>24 tried to do that before?</p> <p>25 A I have looked for other studies and that's</p>	<p style="text-align: right;">Page 229</p> <p>1 what I'm saying in 11 that is new.</p> <p>2 Q You're saying that test could have been done</p> <p>3 by Ethicon?</p> <p>4 A Yes.</p> <p>5 Q But somebody at Ethicon would actually have</p> <p>6 to believe that this cobalt study that you</p> <p>7 referenced and the solutions are what</p> <p>8 actually occurs from macrophages at an</p> <p>9 unknown concentration in the body, correct?</p> <p>10 MR. KUNTZ: Objection.</p> <p>11 A Yes. And there is some well-trained</p> <p>12 scientists at Ethicon. Those papers have</p> <p>13 been cited dozens of times and are well</p> <p>14 established in the field. They are well</p> <p>15 known in the field. Those papers were</p> <p>16 instrumental in discovering the problem of</p> <p>17 the instability of polyether urethane</p> <p>18 catheter leads, that these leads would</p> <p>19 oxidize, degrade, and in some cases fail.</p> <p>20 Those products were withdrawn from the</p> <p>21 market.</p> <p>22 So if I were at Ethicon, and I knew that</p> <p>23 story, I would be very worried about this,</p> <p>24 because it's the same type of problem, a</p> <p>25 chemical attack. It's just an environmental</p>

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<p style="text-align: right;">Page 230</p> <p>1 stress cracking problem, where you have an 2 oxidative environment and materials sensitive 3 to oxidation and mechanical forces. All of 4 those can lead to this environmental stress 5 cracking in device failure. 6 So if I were at Ethicon and I knew of 7 those problems with those urethane catheter 8 leads, one of the first things I would have 9 done is tested these meshes in this oxidative 10 environment so I would know. 11 BY MR. SNELL: 12 Q The urethane catheters, were those Ethicon 13 products? 14 A No. But a good biomaterials scientist 15 recognizes that these are two polymers that 16 are sensitive to oxidation. And I would at 17 least want to know -- I would want to know, 18 does it degrade, does it oxidize, does it 19 degrade. I think you have to ask that 20 question when you're designing a biomedical 21 device, what's the material made of and is 22 that a problem. 23 Q Well, there could be folks at Ethicon who 24 have relevant experience who look at the 25 paper by Anderson and this cobalt solution,</p>	<p style="text-align: right;">Page 232</p> <p>1 trial and tell the Perry jury that based on 2 the testing you did on that single TVT device 3 that there could be degradation in the human 4 body by a certain time point? 5 MR. KUNTZ: Objection. 6 A I've not testified and I don't plan -- I've 7 been saying and I still say that it's 8 unpredictable. There is no certain time 9 point. It's unpredictable. 10 BY MR. SNELL: 11 Q Okay. I just want to make sure I understand 12 how far you were going to try to take this 13 study. 14 Just so we're crystal clear, you're not 15 going to walk into that trial and say, at one 16 year, you can see degradation from the TVT 17 mesh, and I know it because of the study I 18 did on the TVT device? 19 A No, I'm not saying that. 20 Q Okay. Did you do power calculations on your 21 TVT device study? 22 A It's an in vitro test. We typically do power 23 calculations on preclinical studies. But in 24 the in vitro test, it's in vitro, where it's 25 -- you know, it's --</p>
<p style="text-align: right;">Page 231</p> <p>1 and say that test doesn't actually look like 2 it or is representative of the foreign body 3 reaction in the body. I mean, couldn't 4 scientists come to that conclusion? 5 A They could. But, again, this is a 6 well-accepted test that's been cited a lot 7 and used a lot. I think it should at least 8 raise some questions, especially when you 9 have your own studies showing evidence of 10 oxidation. So it's not only the literature, 11 but it's also these own suture studies, the 12 dog study, Guidon study, that showed evidence 13 of oxidation that should have sent off some 14 red flags, hey, this material is sensitive to 15 oxidation, why don't we test it. That is 16 what I am saying. 17 MR. SNELL: Let's take a break 18 here. We've been going for a while. 19 (A brief recess is taken from 20 4:30 to 4:40 p.m.) 21 BY MR. SNELL: 22 Q Doctor, I want to circle back around to your 23 test, the testing that you were involved in. 24 I just want to make sure that based on 25 that test, you're not going to come into</p>	<p style="text-align: right;">Page 233</p> <p>1 Q You need to do power calculations on the 2 front end of this test if you're going to try 3 to do statistical significant testing on the 4 back end, isn't that correct? 5 A My experience with power calculations, again, 6 is typically in an in vivo study where we 7 estimate -- it's so that we ensure that our 8 study is power enough. If we estimate a 9 certain variance in a certain number is 10 10 percent, we want to be able to power our 11 study to make sure that we can see that 12 10-percent effect. 13 But this is an in vitro study, so, well, 14 we did the study, and either we will see a 15 significant difference or we won't. That's 16 what it is. If we don't see a significant 17 difference, then maybe the study wasn't 18 underpowered, but we report that it is if 19 it's not significant. But it's either 20 significant or it's not. 21 I mean, the reason you do a power study 22 in a preclinical study is to make sure you 23 have got enough animals to do your study. In 24 an in vitro study, well, if we don't see 25 significant differences in the in vitro</p>

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<p style="text-align: right;">Page 234</p> <p>1 study, then our conclusion would be that it's 2 just not a significant difference. 3 Q Isn't it true, Doctor, that if you do not do 4 power calculations on the front end of a 5 study, you can't say that there are 6 statistically significant findings on the 7 back end, because you haven't even assessed 8 whether you have an adequately powered study? 9 MR. KUNTZ: Objection. 10 A I don't think that's true in in vitro 11 studies. I don't see people doing this. I 12 don't see papers where people power their in 13 vitro studies. We typically do enough 14 replicates that we can calculate a standard 15 deviation and run an ANOVA or a t-test or 16 something, but we don't -- in a clinical 17 trial and in an animal study, we do power 18 analysis all the time, but I just -- I 19 don't -- 20 BY MR. SNELL: 21 Q Did you estimate the potential rate of error 22 in your study before it was done? 23 A Potential rate of error in -- 24 Q In finding discrepant findings? 25 A I just don't know where you are going with</p>	<p style="text-align: right;">Page 236</p> <p>1 can't see differences, you don't know -- it's 2 part of justifying the numbers of animals 3 that you're going to use in your test. But 4 if you have two sets of data, you can compare 5 whether they are statistically different or 6 not. This is what people do. It's an in 7 vitro test. I just don't know where you are 8 coming from. 9 Q When you do studies, you want to have 10 adequate sample sizes so that you can tell if 11 the results are meaningful. That's a fair 12 statement, right? 13 A Yes, but you can tell if the results are 14 significantly different if you see a 15 significant difference. You can calculate a 16 P value. You can do a t-test. You can do an 17 ANOVA on that date. If you don't see a 18 significant difference, then one reason could 19 be you didn't have enough replicates. But if 20 you see a significant difference, I don't 21 understand how it's not significant. If you 22 see a significant difference between two 23 groups, they're different. That means the 24 differences are -- I don't understand. I 25 mean, this is like statistics that you learn</p>
<p style="text-align: right;">Page 235</p> <p>1 this. 2 Q Did you do it or didn't you do it? Did you 3 do a calculation to assess the potential rate 4 of error before you started that study on the 5 TVT device? 6 A We didn't do that calculation. 7 Q Did you estimate the variance as you noted 8 earlier? 9 A But this isn't the way statistics works. I 10 mean, if we have two populations, we can 11 compare by a t-test. We can compare those 12 populations and draw within -- we assess P to 13 be .05, and so with this value of P, we can 14 say it's significant or not significant. 15 That's typically what people do in in vitro 16 studies. We say P is .05, and then we do 17 this -- we can calculate a P value. You can 18 do it either way. 19 But if you have two populations, you can 20 compare those populations using statistical 21 analyses. My experience with these power 22 analyses is a lot of it comes down to an 23 ethics concern. It's not ethical to do an 24 animal study that is insufficiently powered. 25 Because if you do the study, and you</p>	<p style="text-align: right;">Page 237</p> <p>1 in school. I mean, comparing two 2 populations. 3 Q Yeah, but here the two populations was a TVT 4 device and a polypropylene pellet. It wasn't 5 100 TVT devices and 100 pellets, was it? 6 A You are so confused on statistics. I made 7 this clear. We tested one exemplar, but we 8 cut multiple pieces from each exemplar. So 9 we have replicates. So we can say, 10 statistically, in that mesh that we tested is 11 there more oxidation from the FTIR spectra at 12 week five compared to week four compared to 13 these other weeks. 14 We can do that test through even just -- 15 we could do a two-way ANOVA to compare 16 changes in time and changes in the mesh or 17 between groups and as a function of time. We 18 can do that analysis and that can be -- 19 that's what people do all the time. 20 Q You can't do that analysis as between the 21 control, though, because you didn't run all 22 of the same tests at the same time, correct? 23 A I don't remember the details of that. We ran 24 the control went out to four weeks. We ran 25 the TVT out to five, and I think we might</p>

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<p style="text-align: right;">Page 238</p> <p>1 have had one that went to six weeks, but we 2 just didn't have enough sample to go out that 3 far. 4 But we can do all of these statistical 5 analysis, and I will bring it to trial, and 6 you can come at me with whatever you want 7 about statistics, but I just don't see where 8 you are coming from with this. I mean, we 9 can do a statistical test to see whether 10 there is differences at least in the function 11 of time. That's how we are going to assess 12 whether it is induced is the amount of 13 oxidation at week five significantly greater 14 than what we see at weeks, four, three, two, 15 one or zero. 16 Q That hasn't been done, though, to this point? 17 Or you didn't bring that with you today, 18 right? 19 A It hasn't been done. We're working on it. 20 Q The tensile string, is that anything that you 21 tested in this test of the TVT versus the 22 control? 23 MR. KUNTZ: Objection. 24 A We didn't measure tinsel strength. This 25 takes a lot of material. And, again, it</p>	<p style="text-align: right;">Page 240</p> <p>1 piece of mesh in Mrs. Perry's body became 2 unstable from a polymer standpoint? 3 A No, I'm not. 4 Q Are you aware of any evidence that the piece 5 of mesh in Mrs. Perry became brittle? 6 A No, I'm not aware of that. 7 Q Are you aware of any evidence that the piece 8 of mesh in Mrs. Perry degraded? 9 A No. 10 Q I didn't ask you at the beginning. Have you 11 given testimony at all since the Huskey trial 12 as an expert -- 13 A I provided this listing. 14 Q -- against anybody? I think you're right. 15 MR. KUNTZ: He gave you an 16 updated copy since the Huskey trial. I think 17 you have it. 18 A I gave testimony in Boston Scientific since 19 the Huskey trial. 20 MR. SNELL: I have it right 21 here. I'm going to mark it. 22 (Deposition Exhibit No. 5 was 23 marked for identification.) 24 BY MR. SNELL: 25 Q Doctor, I'm handing you Exhibit 5. Tell me</p>
<p style="text-align: right;">Page 239</p> <p>1 doesn't answer the question of whether it can 2 be oxidized. Tensile strength is a bulk 3 test. So because it is a bulk test, it's 4 testing the whole material. You may or may 5 not see -- the problem with doing a tensile 6 strength test is -- 7 MR. SNELL: Can I move to 8 strike? I don't want to keep you here later 9 than I have to. It was a yes or no really. 10 BY MR. SNELL: 11 Q Do you do tensile strength? 12 A No. 13 Q All right. Did you do any elongation testing 14 in your -- 15 A No. 16 Q I don't see it in your opinion, but I just 17 want to confirm this. You're not going to be 18 giving any testimony on what a suitable 19 alternative device for the treatment of 20 stress urinary incontinence was that was 21 equally safe and effective as TVT Abbrevio; is 22 that correct? 23 A I did not testify on that and I don't plan 24 to. 25 Q Okay. Are you aware of any evidence that the</p>	<p style="text-align: right;">Page 241</p> <p>1 what that is, please. 2 A This is a listing of cases in which I 3 provided testimony in the last four years. 4 And there are five cases listed here in 2013 5 and 2014. 6 MR. SNELL: I'd like to mark 7 what I believe is your CV as the next 8 exhibit. 9 (Deposition Exhibit No. 6 was 10 marked for identification.) 11 BY MR. SNELL: 12 Q Doctor, I'm handing you Exhibit No. 6. If 13 you would just identify that for the record. 14 A This is my CV. It lists all of my academic 15 and professional experience. 16 Q That's current? 17 A Yes. 18 Q Okay. Earlier you talked about environmental 19 stress cracking? 20 A Yes. 21 Q Is that something you need to look at on SEM 22 to assess? 23 A I would assess environmental stress cracking 24 by SEM. There are other methods as well, but 25 SEM is one.</p>

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<p style="text-align: right;">Page 242</p> <p>1 Q What are the other methods?</p> <p>2 A The microscopy methods with Dr. Iakovlev.</p> <p>3 Q Are you aware of any evidence that the piece</p> <p>4 of mesh in Mrs. Perry has or had</p> <p>5 environmental stress cracking?</p> <p>6 A I'm not aware of any evidence.</p> <p>7 Q Earlier we talked about the concept of</p> <p>8 macrophages in foreign giant body cells being</p> <p>9 quiescent?</p> <p>10 A Yes.</p> <p>11 Q You are aware that those cells can be</p> <p>12 quiescent, correct?</p> <p>13 A I'm aware that this is an active area of</p> <p>14 investigation. I'm aware that there is a lot</p> <p>15 of research activity trying to make these</p> <p>16 cells quiescent or inactivate them. I'm not</p> <p>17 aware of any reports that have definitely</p> <p>18 proven they're quiescent or what makes them</p> <p>19 quiescent. I would be happy to look at it.</p> <p>20 I'm familiar with this idea, but I'm not</p> <p>21 familiar with any studies that have proven</p> <p>22 that or shown under what conditions that can</p> <p>23 occur.</p> <p>24 Q You are aware actually that scientists are</p> <p>25 able to now incubate and generate quiescent</p>	<p style="text-align: right;">Page 244</p> <p>1 A We can buy those from companies. There is an</p> <p>2 immortalized cell line that you can buy.</p> <p>3 Q So my question to you, then, is, do you know</p> <p>4 whether there are available for purchase or</p> <p>5 use quiescent macrophage cells?</p> <p>6 A I don't know. I've never purchased them, but</p> <p>7 that doesn't mean that they happen in the</p> <p>8 human body. Again, without seeing a</p> <p>9 document, it's difficult to comment on that.</p> <p>10 Q How would one definitively prove that</p> <p>11 macrophages in giant cells become quiescent</p> <p>12 in the body?</p> <p>13 A Well, I would challenge it with a foreign</p> <p>14 body, and different time points, harvest the</p> <p>15 cells, and stain for myeloperoxidase. But</p> <p>16 it's -- to assess that they are actually</p> <p>17 quiescent -- I mean, you have to count the</p> <p>18 number of cells, and then look at the amount</p> <p>19 of myeloperoxidase, look for degradation. It</p> <p>20 would be difficult to show that they are</p> <p>21 completely quiescent.</p> <p>22 Q So what would you have to do to prove that</p> <p>23 those cells are activated every day of the</p> <p>24 year for ten years? You would have to do the</p> <p>25 same test, wouldn't you?</p>
<p style="text-align: right;">Page 243</p> <p>1 tissue macrophages for use in studies? Don't</p> <p>2 you know that?</p> <p>3 A Well, I would like to see the document you're</p> <p>4 referring to. I just said I haven't seen</p> <p>5 that. I am aware of this idea, but I haven't</p> <p>6 seen that study. I would be happy to look at</p> <p>7 it, but I --</p> <p>8 Q My question is not pertaining to a specific</p> <p>9 study. It's do you know whether scientists</p> <p>10 have generated incubated quiescent tissue</p> <p>11 macrophages for use in studies?</p> <p>12 A I'm not sure what you're referring to. I</p> <p>13 mean, I would have to see a study to -- I'm</p> <p>14 aware of this area of research, but I can't</p> <p>15 comment on it without talking about a</p> <p>16 specific study at least. What am I going to</p> <p>17 say? I don't know where --</p> <p>18 Q Let me ask you this. You know that</p> <p>19 scientists manufacture different cell lines</p> <p>20 for use in studies, correct?</p> <p>21 A There are different permanent cell lines that</p> <p>22 are used in cell culture. I use them in my</p> <p>23 own lab.</p> <p>24 Q So somebody, scientists or companies make</p> <p>25 those, correct?</p>	<p style="text-align: right;">Page 245</p> <p>1 A We talked about this earlier. What I know is</p> <p>2 Dr. Iakovlev, whenever we stain for</p> <p>3 myeloperoxidase, we see it. So does that</p> <p>4 conclusively prove that every cell is always</p> <p>5 -- Dr. Anderson's 2008 review says that these</p> <p>6 cells are activated and adherent, and this</p> <p>7 reaction doesn't stop. That's what he says.</p> <p>8 Q How is that proof? What test has been done</p> <p>9 under the proper methodology that shows that</p> <p>10 those cells are always activated every day</p> <p>11 for a long period of time? Has anybody done</p> <p>12 such a test?</p> <p>13 A Not that I know of. But why would they stop?</p> <p>14 Why would they --</p> <p>15 Q Well, I understand that Dr. Anderson may</p> <p>16 believe that or he wrote something to that</p> <p>17 effect. But has that methodology been tested</p> <p>18 to show that they are always in an activated</p> <p>19 state day after day after day?</p> <p>20 A All I can say is that in my experience with</p> <p>21 this is that they are activated. When I</p> <p>22 talked to Dr. Iakovlev, did you stain for</p> <p>23 myeloperoxidase, his response was, why would</p> <p>24 I stain for myeloperoxidase, it has to be</p> <p>25 there.</p>

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<p style="text-align: right;">Page 246</p> <p>1 Q Dr. Iakovlev assumes it's there. But he has 2 not tested for myeloperoxidase on a 3 continuous basis, daily or weekly basis in 4 samples? 5 A I tell you what, I think most people will be 6 convinced by it. 7 Q Can you answer that question, please? That 8 is what Dr. Iakovlev believes, right? 9 A Yeah. 10 Q But has he tested for myeloperoxidase in the 11 same samples longitudinally week after week 12 after week after week to see that those are 13 activated? 14 A Not to my knowledge. 15 Q All right. And you haven't done that type of 16 testing, correct? 17 A No. But in my experience, when I see 18 macrophages and stain for myeloperoxidase, 19 I've not seen this type of stain. I need to 20 qualify my comment. When I see this adherent 21 macrophages in the foreign giant body cells 22 in my work, they appear to be activated. 23 Q All right. You can see macrophages and 24 they're not activated. That is well known, 25 correct?</p>	<p style="text-align: right;">Page 248</p> <p>1 A You already asked this. I said I don't know 2 of a study that showed that. I'm just going 3 from my own experience. 4 Q Do you know if Dr. Iakovlev has done any type 5 of longitudinal study of myeloperoxidase and 6 what it should show when properly applied to 7 samples from the same source over time? 8 A I mean, he's a pathologist. He looks at 9 patient explants. You can't do a study like 10 that in patients, so I don't believe that he 11 has done that study. 12 Q Did you bring anything else that we haven't 13 marked? 14 A I think that's it. 15 Q When you do statistical significance testing, 16 do you try to generate confident symbols as 17 well? 18 A Sometimes. It depends on what we're trying 19 to do. Sometimes when we establish P at .05, 20 sometimes we can calculate a P value. We've 21 done several different things. 22 Q Have you actually personally ever calculated 23 a Bonferroni correction for multiple 24 comparison? 25 A When I was in graduate school. My students</p>
<p style="text-align: right;">Page 247</p> <p>1 A I don't know that I would say that that is 2 well-known. I don't know under what 3 conditions -- I mean, I would have to see a 4 study. 5 Q Well, let me make it simple. Can macrophages 6 be present and they're not activated? 7 A In theory, it's possible. I'm just going by 8 my own experience. When I see these adherent 9 macrophages, they're activated. They're 10 secreting this myeloperoxidase. There is 11 degradation. That is what I've seen. I will 12 be happy to look at an example where that is 13 not the case, but -- 14 Q If there are chronic inflammatory cells 15 present, that does not necessarily mean that 16 they are active. Is that a fair statement? 17 A It's my opinion that they are active. I 18 mean, I -- can I say that there is a study 19 showing that they are always active all the 20 time, no. But I believe they are active 21 unless somebody shows they are not, and I 22 would like to know under what conditions made 23 them not active. 24 Q There is no test or study that shows that 25 these inflammatory cells are always active?</p>	<p style="text-align: right;">Page 249</p> <p>1 do those calculations now, and I review them. 2 There are software programs that you can use 3 to do this. It's pretty routine, I think. 4 Q The software plugs in the number of tests and 5 the time points and it generates -- 6 A We can do this with software, yeah. 7 Q You haven't published or presented on this 8 test, correct, that was done with the TVT 9 device and the pellet control? 10 A We presented it at the AICHE annual meeting. 11 And I think those slides are on the reliance 12 list. 13 Q For the TVT? 14 A In that presentation, we did not identify the 15 source of the mesh. 16 MR. KUNTZ: I don't think that's 17 on there, Burt. We will get it to you, 18 though. 19 A We called it mesh 1, 2 and 3. We did not 20 identify it as TVT. 21 BY MR. SNELL: 22 Q Do you know if it was TVT or would you have 23 to go back and look? 24 A Yes, it was TVT. We chose not to disclose 25 that at that meeting.</p>

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<p>1 Q Where was this at?</p> <p>2 A The AICHE, it's the American Institute of</p> <p>3 Chemical Engineers. If you would like, I can</p> <p>4 circle it on my CV. Would that help you?</p> <p>5 Q Sure. That's fine. Or if you just want to</p> <p>6 look at your CV and tell me what page or</p> <p>7 number.</p> <p>8 A That's fine too. On the CV, it's</p> <p>9 presentation number 154.</p> <p>10 Q Was that a presentation that you actually</p> <p>11 gave and presented or did someone else do it?</p> <p>12 A Dr. Dunn and I both gave the presentation.</p> <p>13 Q Was it presented orally?</p> <p>14 A It was.</p> <p>15 Q Okay. So I would like to request a copy of</p> <p>16 that.</p> <p>17 Did you have to prepare a manuscript in</p> <p>18 connection with that?</p> <p>19 A No. We submitted a short abstract, which is</p> <p>20 available online. We elected not to submit</p> <p>21 an extended abstract.</p> <p>22 Q What was the reason why you didn't submit an</p> <p>23 extended abstract?</p> <p>24 A We typically don't do that for that meeting.</p> <p>25 Q Is that the only presentation you have made</p>	<p>1 to problems such as pain, erosion. The basis</p> <p>2 for this opinion is the Clave, Costello, Wood</p> <p>3 papers where they show changes in the mesh,</p> <p>4 and then how that resulted in degradation.</p> <p>5 And these are all complications, so these are</p> <p>6 meshes that failed.</p> <p>7 And my opinion is that these changes in</p> <p>8 the mesh contributed to those complications</p> <p>9 like pain and erosion. Brittle plastic can</p> <p>10 cause pain. Embrittlement can cause stress</p> <p>11 shielding between the host tissue and the</p> <p>12 implant, which can lead to poor integration,</p> <p>13 erosions, and things like that. These are</p> <p>14 all points that I made previously in Huskey.</p> <p>15 Q In Huskey, though, you didn't testify about</p> <p>16 that at trial as I recall it because you're</p> <p>17 not a medical doctor. Is that consistent</p> <p>18 with your recollection?</p> <p>19 MR. KUNTZ: Objection. Go</p> <p>20 ahead.</p> <p>21 A I think the Judge may have limited what I</p> <p>22 would have liked to have said, but I believe</p> <p>23 it's in the deposition. I don't think</p> <p>24 there is any change in what I'm saying, in</p> <p>25 what I've been saying in these depositions.</p>
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<p>1 concerning the TVT mesh?</p> <p>2 A Yes.</p> <p>3 Q Have you made any other presentations that</p> <p>4 concern transvaginal mesh?</p> <p>5 A That's the only one.</p> <p>6 Q On opinion number one, you say chemical</p> <p>7 degradation, embrittlement, structural</p> <p>8 degradation and other changes.</p> <p>9 A Yes.</p> <p>10 Q Are there any other changes that you're</p> <p>11 referencing that you're going to be talking</p> <p>12 about at trial in the Perry case? That just</p> <p>13 seems kind of broad based, and I want to make</p> <p>14 sure I understand where you're coming from</p> <p>15 with what other changes means.</p> <p>16 A I would probably say I think structural</p> <p>17 degradation, embrittlement, and chemical</p> <p>18 degradation are the primary ones that come to</p> <p>19 mind that I've testified about.</p> <p>20 Q Okay. And number two where it seems to --</p> <p>21 are you going to try to opine that certain</p> <p>22 complications occur in patients like chronic</p> <p>23 inflammation, pain and dyspareunia because of</p> <p>24 the mesh?</p> <p>25 A I'm saying that changes in the mesh can lead</p>	<p>1 Q And just so I'm clear, you didn't conduct any</p> <p>2 type of differential diagnosis to assess the</p> <p>3 cause of dyspareunia or pain or the potential</p> <p>4 causes, correct?</p> <p>5 A No.</p> <p>6 Q You didn't rule out any other cause or</p> <p>7 potential causes?</p> <p>8 A I didn't rule out any other causes.</p> <p>9 Q And you didn't investigate the rates of</p> <p>10 dyspareunia or pain in the general background</p> <p>11 and compare them to these cohorts?</p> <p>12 A I did not.</p> <p>13 Q And in Clave, it's fair to state that one</p> <p>14 cannot say that the complications did not</p> <p>15 occur before the degradation; is that right?</p> <p>16 A It's not clear from Clave the timing of those</p> <p>17 events. My opinion is that these changes in</p> <p>18 the mesh led to those events. The mesh</p> <p>19 changed and there was an adverse event.</p> <p>20 Q And the adverse events are also you mention</p> <p>21 on items number eight and nine, extrusions,</p> <p>22 inflammation, pain, and you mention erosions</p> <p>23 on nine, correct?</p> <p>24 A Yes.</p> <p>25 Q You didn't not do any differential diagnoses</p>

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<p>1 on those, correct?</p> <p>2 A No.</p> <p>3 Q You didn't assess causation by ruling in or</p> <p>4 ruling out different causes, correct?</p> <p>5 A No, I didn't do that.</p> <p>6 Q In the testing that Dr. Kammerer did we</p> <p>7 talked about earlier, where in the first</p> <p>8 5 percent of elongation of the mesh, the</p> <p>9 mechanical-cut and the laser-cut were</p> <p>10 similar, do you dispute that finding?</p> <p>11 A I don't dispute the finding that of the very</p> <p>12 low elongation. They are similar but --</p> <p>13 Q Okay. That's my question.</p> <p>14 A Yeah. Okay.</p> <p>15 Q Did you look at the clinical expert report</p> <p>16 that was done by two medical doctors at</p> <p>17 Ethicon with regard to the laser-cut mesh and</p> <p>18 elongation?</p> <p>19 A I think I reviewed that document, but I can't</p> <p>20 remember what it said right now.</p> <p>21 Q Did that document affect your opinions?</p> <p>22 A I would have to look at it again to see what</p> <p>23 it says. I don't remember.</p> <p>24 Q Did you consider whether either of those</p> <p>25 doctors had any experience implanting slings</p>	<p>1 suggested I talk to Dmochowski, but I</p> <p>2 understand he might have been a defense</p> <p>3 witness, so I haven't done that. I don't</p> <p>4 think I'm supposed to do that. So I have</p> <p>5 reached out to them, but it hasn't moved</p> <p>6 forward.</p> <p>7 Q Has Dr. Dmochowski been an expert in any of</p> <p>8 the other cases you're involved in?</p> <p>9 A I don't know for sure. I don't know if he is</p> <p>10 an expert or not, because I have to resolve</p> <p>11 this before I can contact him. But I have</p> <p>12 reached out to that group at Vanderbilt.</p> <p>13 MR. KUNTZ: I wonder if he has</p> <p>14 disclosed his stuff to Vanderbilt.</p> <p>15 (Deposition Exhibit No. 7 was</p> <p>16 marked for identification.)</p> <p>17 BY MR. SNELL:</p> <p>18 Q I am handing you Exhibit 7 from Vanderbilt.</p> <p>19 Do you recognize this to be from the</p> <p>20 Vanderbilt Health Website?</p> <p>21 A This appears to be urogynecology in the way</p> <p>22 it's printed. I think that's what it is.</p> <p>23 MR. KUNTZ: I'm going to object.</p> <p>24 This is not a complete printout. Are you</p> <p>25 going to show him the part two where they</p>
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<p>1 in women?</p> <p>2 A I would have to look at the document. I just</p> <p>3 don't remember the documents to answer these</p> <p>4 questions. I'd have to look at it.</p> <p>5 Q Have you ever consulted with a</p> <p>6 urogynecologist or a urologist who has</p> <p>7 experience implanting mesh slings to discuss</p> <p>8 with them or learn from them the forces that</p> <p>9 are in play during implantation?</p> <p>10 A No, I have not done that. I relied on the</p> <p>11 Ethicon documents.</p> <p>12 Q The e-mails you were talking about?</p> <p>13 A And the other documents, the reports, the</p> <p>14 papers.</p> <p>15 Q Do you even know Dr. Dmochowski here at</p> <p>16 Vanderbilt?</p> <p>17 A I don't know him.</p> <p>18 Q Do you know that Dr. Dmochowski uses</p> <p>19 polypropylene mesh slings?</p> <p>20 A That's my understanding.</p> <p>21 Q Have you ever written or said anything to any</p> <p>22 of the doctors here at Vanderbilt to apprise</p> <p>23 them of what your opinions are?</p> <p>24 A I have. I have contacted -- there is a</p> <p>25 urogynecologist in the group there, and she e</p>	<p>1 talk about all the mesh complication that</p> <p>2 they treat? Are we going to get the full</p> <p>3 document or just part of it?</p> <p>4 MR. SNELL: You can do whatever</p> <p>5 you want. This is Page 3 of 3.</p> <p>6 MR. KUNTZ: Well, I'm going to</p> <p>7 object to an incomplete document. It's a</p> <p>8 printout of part of the website.</p> <p>9 BY MR. SNELL:</p> <p>10 Q At the top it says, surgical treatments for</p> <p>11 stress urinary incontinence, including mid</p> <p>12 urethral slings. Do you see that?</p> <p>13 A Yes, I'm aware of this. I've seen it.</p> <p>14 Q Well, I guess my question to you is is this a</p> <p>15 website that you visited on the Vanderbilt</p> <p>16 website?</p> <p>17 A I believe I did, because I had to find who to</p> <p>18 contact, but I believe they also do a number</p> <p>19 of revisions.</p> <p>20 MR. SNELL: Move to strike.</p> <p>21 THE WITNESS: Well, you asked.</p> <p>22 I'm sorry.</p> <p>23 BY MR. SNELL:</p> <p>24 Q My question was straight forward.</p> <p>25 A They always are.</p>

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<p style="text-align: right;">Page 258</p> <p>1 Q They really are, sir.</p> <p>2 MR. KUNTZ: Hold on. I'm going</p> <p>3 to object. You are showing him one document,</p> <p>4 and I just made my objection. It is not a</p> <p>5 straight forward question when you're not</p> <p>6 showing him the whole website. And he just</p> <p>7 said where is the website that shows all of</p> <p>8 the complications they're treating for mesh.</p> <p>9 So that is not a straight forward question.</p> <p>10 MR. SNELL: That's not even a</p> <p>11 proper objection. That's not a proper</p> <p>12 objection in California. That's beyond a</p> <p>13 speaking objection.</p> <p>14 MR. KUNTZ: You just said all of</p> <p>15 my questions are straight forward. And this</p> <p>16 is very much a trick question and not a</p> <p>17 straight forward question. So don't make</p> <p>18 your comments unless you --</p> <p>19 MR. SNELL: Let's try it again</p> <p>20 and knock off the ridiculous speaking</p> <p>21 objections.</p> <p>22 MR. KUNTZ: Show him the whole</p> <p>23 website.</p> <p>24 MR. SNELL: Give the man a</p> <p>25 computer. You can have him look at anything.</p>	<p style="text-align: right;">Page 260</p> <p>1 stopped because it's not proper for me to --</p> <p>2 I don't know whether he is a defense witness</p> <p>3 or not, so I would have to resolve this</p> <p>4 before I would really do anything.</p> <p>5 Q You did speak to a female urogynecologist?</p> <p>6 A Yes. I can't remember her name.</p> <p>7 Q Or do you know if she was a urologist?</p> <p>8 A I can't remember. She was in this group.</p> <p>9 She has experience with mesh revisions. And</p> <p>10 one of my students, one of my medical</p> <p>11 students, did a rotation with her, and I</p> <p>12 contacted her, I think, in September, but I</p> <p>13 dropped it because of this concern about</p> <p>14 litigation.</p> <p>15 Q Okay. Do you have any understanding of the</p> <p>16 antioxidants that are in the mesh for the TVT</p> <p>17 Abbrevio?</p> <p>18 A To my knowledge, they are the same as they</p> <p>19 are in proline resin that I talked about at</p> <p>20 trial.</p> <p>21 Q Okay. One of the opinions you gave in Huskey</p> <p>22 was less mesh is better; is that correct?</p> <p>23 A That's correct.</p> <p>24 Q Why don't you give that opinion here?</p> <p>25 A Why don't I give that opinion?</p>
<p style="text-align: right;">Page 259</p> <p>1 MR. KUNTZ: You bring documents</p> <p>2 and ask him questions. My job is to show up</p> <p>3 with --</p> <p>4 MR. SNELL: You are wasting my</p> <p>5 time. You're giving speaking objections that</p> <p>6 are absolutely improper in California.</p> <p>7 MR. KUNTZ: You are asking trick</p> <p>8 questions, and that's what he told you.</p> <p>9 MR. SNELL: It's not a trick</p> <p>10 question.</p> <p>11 BY MR. SNELL:</p> <p>12 Q Doctor, I read to you surgical treatments for</p> <p>13 stress urinary incontinence include</p> <p>14 mid urethral slings. Did you see that?</p> <p>15 A Yeah, I've seen it.</p> <p>16 Q My question was, have you seen this part of</p> <p>17 the website?</p> <p>18 A I believe so, but it's a printout. It</p> <p>19 doesn't really look the same. I have been on</p> <p>20 that website.</p> <p>21 Q Under what circumstance, would you have gone</p> <p>22 to the website?</p> <p>23 A I was reaching out to that group to discuss</p> <p>24 mesh. I have contacted an OB in that group.</p> <p>25 I can't remember the name right now, but I</p>	<p style="text-align: right;">Page 261</p> <p>1 Q Why aren't you giving that opinion here?</p> <p>2 A I don't think that was specified as an</p> <p>3 opinion. I don't recall that. I thought it</p> <p>4 was in the body of the report. I don't</p> <p>5 remember that being spelled out as a specific</p> <p>6 opinion.</p> <p>7 Q Do you know Abbrevio uses less mesh than</p> <p>8 TVT-O, don't you?</p> <p>9 A What do you mean by uses less mesh? The area</p> <p>10 is smaller, but what about the --</p> <p>11 Q Well, answer my question.</p> <p>12 A I'm trying to clear up the way you're asking</p> <p>13 it. I asking you, do you mean as it has a</p> <p>14 different density or it's a less area?</p> <p>15 That's what I'm asking.</p> <p>16 Q Does TVT Abbrevio have less mesh than the TVT</p> <p>17 obturator?</p> <p>18 A I mean, it has less surface area of mesh, but</p> <p>19 I believe the density of that mesh is still</p> <p>20 the same.</p> <p>21 Q When you say less surface area, you mean it's</p> <p>22 not as long as the TVT-O, correct?</p> <p>23 A Yes, I think that's what I mean.</p> <p>24 Q It's still 1.1 sonometers wide approximately;</p> <p>25 is that correct?</p>

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<p>1 A To my knowledge, and I believe the density is 2 the same as well. 3 Q When you say density, what do you mean by 4 that? 5 A Grams per square meter. 6 Q Okay. But we can agree there is less mesh 7 with TVT Abbrevio than TVT-O? 8 A There is less mesh -- the way you say it, I 9 guess it's true. 10 Q Now, do you have an opinion as to whether TVT 11 Abbrevio is the better or a safer device than 12 the TVT-O? 13 MR. KUNTZ: Objection. 14 A No. I'm not comparing it to TVT-O. 15 MR. SNELL: I think I'm about 16 done. Let me look back through and see if 17 there is anything else. 18 (A brief recess is taken from 19 5:30 to 5:40 p.m.) 20 BY MR. SNELL: 21 Q Just a few more questions, Doctor. So I'm 22 going to request that whatever the materials 23 that weren't provided on the testing that was 24 done be provided. I'm going to leave the 25 deposition open.</p>	<p>1 what we have, and preparing for trial, those 2 types of activities. 3 Q All right. Is there a list of analyses that 4 you can tell me or tell the court reporter 5 that you plan to do? 6 A Plan to do testing. 7 Q With the testing or pertaining to this case? 8 A It's the statistical analysis and writing the 9 paper. That's it. 10 Q What will you do if you do the statistical 11 calculations and they turn out to not be 12 statistically significant? 13 A Report it as not significant, like we always 14 do. 15 Q What else? 16 A What do you mean what else? 17 Q What will you do to try to understand why 18 they were not statistically significant? 19 A I don't know. I would have to think about 20 that at the time it -- I don't think that 21 that is what is going to happen. The peak is 22 ten times bigger, and the aragores (phonetic) 23 aren't that -- I believe it's going to be 24 significant, and if it's not, then I will 25 figure out what to do when that happens. I'm</p>
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<p>1 Is there anything you believe is 2 important to your analysis -- 3 MR. KUNTZ: Hold on. We're not 4 leaving the deposition open. 5 MR. SNELL: You can say what you 6 want to say. I'm leaving it open. I don't 7 have all of the documents. 8 MR. KUNTZ: California law is 9 you can argue -- 10 MR. SNELL: I'm not going to 11 argue with you. I'm either right or wrong. 12 MR. KUNTZ: Okay. 13 MR. SNELL: I'm either right or 14 wrong. 15 BY MR. SNELL: 16 Q Is there anything you believe is important in 17 your opinions and analyses that we have not 18 discussed today? 19 A I believe we have discussed everything that 20 is important. 21 Q Now, is there any work that you are planning 22 on doing with this case after today? 23 A No. 24 Q Besides the statistical calculations? 25 A No. No testing is planned, just analyzing</p>	<p>1 not going to misrepresent data. 2 MR. SNELL: That's fine. I'm 3 going to leave the door open. I know counsel 4 has a question or two. 5 MR. ROSEN: I've got one 6 question. 7 CROSS-EXAMINATION 8 BY MR. ROSEN: 9 Q Good evening, Mr. Guelcher. My name is 10 Dr. Rosen. I'm with Boyce Schaeffer 11 Mainieri. We represent Dr. Luu. I just have 12 one question. 13 Do you intend to offer any opinions 14 regarding Dr. Luu at trial in this matter? 15 A I do not. My testimony is about the mesh and 16 how it changes after implantation. 17 MR. ROSEN: That's all. Thank 18 you. 19 MR. KUNTZ: Dr. Guelcher, I have 20 a few questions for you. 21 CROSS-EXAMINATION 22 BY MR. KUNTZ: 23 Q With respect to the studies you've talked 24 about, and the testing you did with Dr. Dunn, 25 in the SEM, FTIR, and XPS, those are all</p>

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<p style="text-align: right;">Page 266</p> <p>1 studies or documents or data that you can 2 review independently of Dr. Dunn, correct? 3 A Yes, that's correct. 4 MR. SNELL: Objection. You've 5 got to give me a chance to object. Leading, 6 compound. Go ahead. 7 BY MR. KUNTZ: 8 Q You repeatedly in your practice are going to 9 have expertise reviewing those types of 10 studies, SEM, FTIR, and XPS? 11 MR. SNELL: Objection. Leading 12 compound. Go ahead. 13 A Yes, I do. 14 Q And if Ethicon did those studies or had those 15 types of documents, you could review those 16 independently, correct? 17 MR. SNELL: Same objections. 18 A Yes, I could. 19 Q The last question I have. Is there any 20 peer-reviewed article that you're aware of 21 that shows or supports the notion that 22 macrophages in foreign body giant cells can 23 be deactivated? 24 A I'm not aware of such an article. 25 MR. KUNTZ: Okay. No more</p>	<p style="text-align: right;">Page 268</p> <p>1 of the response, part of the answer. 2 I'm done. Thank you. 3 (Deposition was adjourned at 5:50 4 p.m.) 5 * * * 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>
<p style="text-align: right;">Page 267</p> <p>1 questions. 2 REDIRECT EXAMINATION 3 BY MR. SNELL: 4 Q Are you aware of any book chapters, any 5 articles in the peer-reviewed literature that 6 says that macrophages can indeed be 7 deactivated? 8 A I'm not aware of those articles. That's what 9 I said earlier. 10 Q But you have seen it in the literature or in 11 books that macrophages can be quiescent? 12 A That's not what I said. I'm familiar with 13 this idea of reprogramming macrophages, but I 14 am not familiar with any studies that have 15 shown that this has been done or under what 16 conditions it happens. I mean, I'm familiar 17 with the idea. I'm just not familiar with 18 such a study is what I'm saying. 19 Q You're not familiar with such a study that 20 shows that macrophages are activated 21 longitudinally every day for years and years? 22 A No one has proven that, but Anderson teaches 23 they're activated when they adhere. That's 24 what it says. 25 MR. SNELL: Move to strike part</p>	<p style="text-align: right;">Page 269</p> <p>1 STATE OF KENTUCKY) 2) 3 COUNTY OF DAVIESS) 4) 5 I, MICHELLE E. KERR, A NOTARY PUBLIC AT LARGE IN 6 AND FOR THE COMMONWEALTH OF KENTUCKY, DO HEREBY 7 CERTIFY: 8 THAT SAID DEPOSITION WAS TAKEN STENOGRAPHICALLY 9 AND ELECTRONICALLY BY ME AND THAT THE TYPEWRITTEN 10 TRANSCRIPT ABOVE IS A TRUE RECORD OF THE 11 TESTIMONY GIVEN; THAT I ALSO RECORDED AND 12 TRANSCRIBED ANY AND ALL OBJECTIONS MADE BY COUNSEL 13 AND THE REASONS THEREFORE; AND THAT I AM NOT A 14 RELATIVE OR EMPLOYEE OR ATTORNEY OR COUNSEL OF ANY 15 OF THE PARTIES, NOR A RELATIVE OR EMPLOYEE OF SUCH 16 ATTORNEY OR COUNSEL, NOR AM I FINANCIALLY INTERESTED 17 IN THIS ACTION. 18 19 20 IN WITNESS WHEREOF, I HAVE HEREUNTO SET MY HAND 21 AND AFFIXED MY NOTARIAL SEAL ON THIS ____ DAY OF 22 DECEMBER, 2014. 23 24 MICHELLE E. KERR, NOTARY PUBLIC 25 My Commission Expires: March 21, 2017 March 21, 2017</p>

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<p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition</p> <p>4 over carefully and make any necessary</p> <p>5 corrections. You should state the reason</p> <p>6 in the appropriate space on the errata</p> <p>7 sheet for any corrections that are made.</p> <p>8 After doing so, please sign</p> <p>9 the errata sheet and date it. It will be</p> <p>10 attached to your deposition.</p> <p>11 It is imperative that you</p> <p>12 return the original errata sheet to the</p> <p>13 deposing attorney within thirty (30) days</p> <p>14 of receipt of the deposition transcript</p> <p>15 by you. If you fail to do so, the</p> <p>16 deposition transcript may be deemed to be</p> <p>17 accurate and may be used in court.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2</p> <p>3 I, _____, do</p> <p>4 hereby certify that I have read the</p> <p>5 foregoing pages, and that the same</p> <p>6 is a correct transcription of the answers</p> <p>7 given by me to the questions therein</p> <p>8 propounded, except for the corrections or</p> <p>9 changes in form or substance, if any,</p> <p>10 noted in the attached Errata Sheet.</p> <p>11</p> <p>12 _____</p> <p>13 SCOTT A. GUELCHER, PH.D. DATE</p> <p>14</p> <p>15 Subscribed and sworn</p> <p>16 to before me this</p> <p>17 _____ day of _____, 20____.</p> <p>18 My commission expires: _____</p> <p>19</p> <p>20 _____</p> <p>21 Notary Public</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
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<p>1 -----</p> <p>2 E R R A T A</p> <p>3 -----</p> <p>4 PAGE LINE CHANGE</p> <p>5 REASON: _____</p> <p>6 REASON: _____</p> <p>7 REASON: _____</p> <p>8 REASON: _____</p> <p>9 REASON: _____</p> <p>10 REASON: _____</p> <p>11 REASON: _____</p> <p>12 REASON: _____</p> <p>13 REASON: _____</p> <p>14 REASON: _____</p> <p>15 REASON: _____</p> <p>16 REASON: _____</p> <p>17 REASON: _____</p> <p>18 REASON: _____</p> <p>19 REASON: _____</p> <p>20 REASON: _____</p> <p>21 REASON: _____</p> <p>22 REASON: _____</p> <p>23 REASON: _____</p> <p>24 REASON: _____</p> <p>25 REASON: _____</p>	<p>1 LAWYER'S NOTES</p> <p>2 PAGE LINE</p> <p>3 _____</p> <p>4 _____</p> <p>5 _____</p> <p>6 _____</p> <p>7 _____</p> <p>8 _____</p> <p>9 _____</p> <p>10 _____</p> <p>11 _____</p> <p>12 _____</p> <p>13 _____</p> <p>14 _____</p> <p>15 _____</p> <p>16 _____</p> <p>17 _____</p> <p>18 _____</p> <p>19 _____</p> <p>20 _____</p> <p>21 _____</p> <p>22 _____</p> <p>23 _____</p> <p>24 _____</p> <p>25 _____</p>

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